UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TRIANTAFYLLOS TAFAS, Plaintiff, v. JON W. DUDAS, et al., Defendants.	)	Civil Action No. 1:07cv846(L) (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, et al., Plaintiffs, v. JON W. DUDAS, et al., Defendants.	)	Civil Action No. 1:07cv1008 (JCC/TRJ)

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IN SUPPORT OF THEIR MOTIONS FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES. iii

TABLE OF ABBREVIATIONS FOR CITATIONS TO COURT FILINGS. xiii

INTRODUCTION. 1

ARGUMENT. 2

I. THE FINAL RULES ARE CONSISTENT WITH THE PATENT ACT. 2

A. The Final Rules Were Promulgated Pursuant to Expressly Delegated Rulemaking Authority and Are Thus Eligible for Chevron Deference. 2

B. Final Rule 78 Places Reasonable Conditions on the Filing of Continuing Applications, Consistent with Section 120 of the Patent Act.. 8

C. Final Rule 114 Comports With Section 132. 12

D. Final Rules 75 and 265 Are Consistent With Section 112.. 14

E. Tafas's Ancillary Patent Act Claims Lack Merit.. 16

II. THE FINAL RULES ARE NOT ARBITRARY OR CAPRICIOUS. 20

A. GSK's "Arbitrary and Capricious" Claims Fail.. 20

B. Tafas's "Arbitrary and Capricious" Claims Fail. 22

III. THE FINAL RULES ARE NOT RETROACTIVE IN THEIR CURRENT APPLICATION. 26

A. The Procedural Nature of the Rules Is Relevant, Even if Not Dispositive. 27

B. The Final Rules Do Not Impair Applicants' Rights. 28

C. The Final Rules Do Not Impose New Duties on Completed Transactions.. 30

IV. GSK'S "ADMINISTRATIVE-LAW BASED TAKINGS CLAIM" FAILS. 32

A. The USPTO Adequately Addressed Takings Issues. 32

B. Any Purported Inadequacy In the USPTO's Explanation Could Not Have Been "Prejudicial Error" Absent Valid Takings Concerns.. 33

1. *Patent Applications Are Not Property Under the Fifth Amendment* 33

2. *No Taking Would Occur Under Lucas or Penn Central*. 35

V. TAFAS'S PATENT CLAUSE CLAIMS FAILS. 37

VI. PLAINTIFFS' VAGUENESS CHALLENGE FAILS AS A MATTER OF LAW. 39

A. Plaintiff's Vagueness Challenge to Rule 265 Fails Even Under the Fair Notice Doctrine. 39

B. Final Rule 265 is Constitutionally Clear. 40

VII. THE FINAL RULES ARE "REASONABLY FORESEEABLE" IN LIGHT OF THE PROPOSED RULES. 42

VIII. THE USPTO COMPLIED WITH THE REGULATORY FLEXIBILITY ACT. 46

CONCLUSION. 50

CERTIFICATE OF SERVICE. 52

TABLE OF AUTHORITIES

Page

CASES

Adams Fruit Co. v. Barrett,
494 U.S. 638 (1990). 3, 15

Agri-Mark, Inc. v. Niro, Inc.,
233 F. Supp. 2d 200 (D. Mass. 2002). 16

Alenco Commc'ns Inc. v. FCC,
201 F.3d 608 (5th Cir. 2000). 47, 49

Am. Bar Ass'n v. FTC,
430 F.3d 457 (D.C. Cir. 2005). 8

Am. Hosp. Ass'n v. Bowen,
834 F.2d 1037 (D.C. Cir. 1987). 5

Animal Legal Defense Fund v. Quigg,
932 F.2d 920 (Fed. Cir. 1991). 6

Application of Rubinfield,
270 F.2d 391 (C.C.P.A. 1959). 14, 15

Associated Fisheries of Me., Inc. v. Daley,
127 F.3d 104 (1st Cir. 1997). 46, 50

Atchison, Topeka & Santa Fe Ry. Co. v. Pena,
44 F.3d 437 (7th Cir. 1994). 2, 7

Bar MK Ranches v. Yuetter,
994 F.2d 735 (10th Cir. 1993). 24

Batterton v. Marshall,
648 F.2d 694 (D.C. Cir. 1980). 5

Bellsouth Telecomms., Inc. v. Southeast Telephone, Inc.,
462 F.3d 650 (6th Cir. 2006). 29

Bergerco Canada v. U.S. Treas. Dep't,
129 F.3d 189 (D.C. Cir. 1997). 29

Brenner v. Ebbert,
398 F.2d 762 (D.C. Cir.),
cert. denied, 393 U.S. 926 (1968). 35

Buckley v. Valeo,
424 U.S. 1 (1976). 38

Burlington Truck Lines, Inc. v. United States,
371 U.S. 156 (1962). 28

Camp v. Pitts,
411 U.S. 138 (1973). 21, 23

Carpenter v. Sec'y of Veterans Affairs,
343 F.3d 1347 (Fed. Cir. 2003). 48

Cathedral Candle Co. v. U.S. Intern. Trade Comm'n,
400 F.3d 1352 (Fed. Cir. 2005). 7

Centigram Commc'ns Corp. v. Lehman,
862 F. Supp. 113 (E.D. Va. 1994). 7

Chadmoore Commc'n v. FCC,
113 F.3d 235 (D.C. Cir. 1997). 29

Chevron USA, Inc. v. NRDC, Inc.,
467 U.S. 837 (1984). . . . . passim

Chrysler Corp. v. Brown,
441 U.S. 281 (1979). 6

Cienega Gardens v. United States,
503 F.3d 1266 (Fed. Cir. 2007). 37

Citizens to Preserve Overton Park, Inc. v. Volpe,
401 U.S. 402 (1971). 28

City of Waukesha v. EPA,
320 F.3d 228 (D.C. Cir. 2003). 45

Combs v. Comm'r of Soc. Sec.,
459 F.3d 640 (6th Cir. 2002). 27

Connolly v. Pens. Benefit Guar'y Corp.,
475 U.S. 211 (1986). 36

Ctr. for Biological Diversity v. NHTSA,
508 F.3d 508 (9th Cir. 2007). 21

DeFerranti v. Lyndmark,
30 App. D.C. 417 (1908). 35

Ex Parte Henriksen,
154 U.S.P.Q. 53 (Bd. of Pat. Appeals 1966). 10

Ex Parte Hull,
191 U.S.P.Q. 157 (Pat. & Trademark Office Bd. App. 1975). 10

FDA v. Brown & Williamson Tobacco Corp.,
529 U.S. 120 (2000).. 8

Fernandez-Vargas v. Gonazles,
126 S. Ct. 2422 (2006).. 32

Fleury v. Clayton,
847 F.2d 1229 (7th Cir. 1988). 29

FMC Corp. v. Hennessy Indus., Inc.,
836 F.2d 521 (Fed. Cir. 1987). 16

Frazier v. Roessel Cine Photo Tech., Inc.,
417 F.3d 1230 (Fed. Cir. 2005). 16

Gen. Elec. Co. v. EPA,
53 F.3d 1324 (D.C. Cir. 1995). 40, 41

Gilmour v. Gates, McDonald & Co.,
382 F.3d 1312 (11th Cir. 2004). 16

Godfrey v. Eames,
68 U.S. 317 (1863).. 9

Grayned v. City of Rockford,
408 U.S. 104 (1972).. 41

In re Bogese,
303 F.3d 1362 (2002).. . . . . 11, 12

In re Daniels,
144 F.3d 1452 (Fed. Cir. 1998). 15

In re Henriksen,
399 F.2d 253 (C.C.P.A. 1968). 10

In re Hogan,
559 F.2d 595 (C.C.P.A. 1977). 10

In re Oetiker,
977 F.2d 1443 (Fed. Cir. 1992). 18

In re Patecell,
19 U.S.P.Q. 2d 139 (Comm'r of Pat. & Trademarks 1991). 34

In re Piasecki,
745 F.2d 1468 (Fed. Cir. 1984). 18

In re Sang Su Lee,
277 F.3d 1338 (Fed. Cir. 2002). 28

In re Warner,
379 F.2d 1011 (C.C.P.A. 1967). 18

INS v. Orlando Ventura,
537 U.S. 12 (2002). 32

INS v. St. Cyr,
533 U.S. 289 (2001). 29

JEM Broadcasting Co. v. FCC,
22 F.3d 320 (D.C. Cir. 1994) 5

Kingsdown Medical Consultants, Ltd. v. Hollister Inc.,
863 F.2d 867 (Fed. Cir. 1988). 10, 11

Lacavera v. Dudas,
441 F.3d 1380 (Fed. Cir. 2006). 7

Landgraf v. USI Film Products,
511 U.S. 244 (1994). . . . . passim

Lechmere, Inc. v. NLRB,
502 U.S. 527 (1992). 4, 5

Long Island Care at Home, Ltd. v. Coke,
— U.S. —, 127 S. Ct. 2339 (2007). 43, 45

Lucas v. South Carolina Coastal Council,
505 U.S. 1003 (1992). 32, 35

MacDonald, Sommer & Frates v. Yolo County,
477 U.S. 340 (1986). 32

Marsh v. Nichols, Shepherd & Co.,
128 U.S. 605 (1888). . . . . passim

Marten v. Yellow Freight Sys., Inc.,
993 F. Supp. 822 (D. Kan. 1998). 16

Merck & Co. v. Kessler,
80 F.3d 1543 (Fed. Cir. 1996). 4, 7, 15

Morall v. DEA,
412 F.3d 165 (D.C. Cir. 2005). 21

Morton v. Ruiz,
415 U.S. 199 (1974).. 6

Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.,
463 U.S. 29 (1983).. . . . . 20, 25, 26

N.Y. State Bar Ass'n v. FTC,
276 F. Supp. 2d 110 (D.D.C. 2003). 8

Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.,
545 U.S. 967 (2005).. . . . . 4, 5, 11

Nat'l Wildlife Found. v. ICC,
850 F.2d 694 (D.C. Cir. 1988). 32

Norton v. Curtiss,
433 F.2d 779 (C.C.P.A. 1970). 3

Nyeholt v. Secretary of Veterans Affairs,
298 F.3d 1350 (Fed. Cir. 2002). 39, 40

Ohio v. EPA,
997 F.2d 1520 (D.C. Cir. 1993). 20

Olim v. Wakinekona,
461 U.S. 238 (1983).. 29

Paulik v. Rizkalla,
760 F.2d 1270 (Fed. Cir. 1985). 10

Penn Central Transp. Co. v. City of New York,
438 U.S. 104 (1978).. 36

Pesquera Mares Australes Ltda. v. United States,
266 F.3d 1372 (Fed. Cir. 2001). 2, 4

Pine Tree Med. Assocs. v. Sec. of Health & Human Servs.,
127 F.3d 118 (1st Cir. 1997). 29

Prometheus Radio Project v. F.C.C.,
373 F.3d 372 (3d Cir. 2004).. 29

Railway Labor Executives Assocation v. National Mediation Board,
29 F.3d 655 (D.C. Cir. 1994). 8

Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric.,
415 F.3d 1078 (9th Cir. 2005).. 47

Rep. of Austria v. Altmann,
541 U.S. 677 (2004).. 27

Ricoh Co. Ltd. v. Nashua Corp.,
1999 WL 88969 (Fed. Cir. 1999).. 10

Ruckelshaus v. Monsanto Co.,
467 U.S. 986 (1984).. . . . . passim

Sac & Fox Nation of Mo. v. Norton,
240 F.3d 1250 (10th Cir. 2001).. 8

Skidmore v. Swift & Co.,
323 U.S. 134 (1944).. 7

South Corp. v. United States,
690 F.2d 1368 (Fed. Cir. 1982). 15

Star Fruits S.N.C. v. United States,
393 F.3d 1277 (Fed. Cir. 2005). 14

Stevens v. Tamai,
366 F.3d 1325 (Fed. Cir. 2004). 7

Symbol Techs., Inc. v. Lemelson Med., Educ., & Res. Found., LP,
422 F.3d 1378 (Fed. Cir. 2005) ("Symbol IV"). 11, 12

Tafas v. Dudas,
511 F. Supp. 2d 652 (E.D. Va. 2007) ("Tafas I"). 22, 47

Tafas v. Dudas,
— F. Supp. 2d —, 2008 WL 112043 (E.D. Va. Jan. 9, 2008) ("Tafas II"). . . . . passim

U.S. Air Tour Ass'n v. Fed. Aviation Admin.,
298 F.3d 997 (D.C. Cir. 2002). 22

U.S. Cellular Corp. v. FCC,
254 F.3d 78 (D.C. Cir. 2001). 46, 49, 50

United States v. Chrysler,
158 F.3d 1350 (D.C. Cir. 1998). 40

United States v. S. Ind. Gas & Elec. Co.,
245 F. Supp. 2d 994 (S.D. Ind. 2003). 41

United States v. Kay,
— F.3d — , 2007 WL 3088140, *19 n.16 (5th Cir. Oct. 24, 2007). 41

United States v. Lanier,
520 U.S. 259 (1997). 40

United States v. Mead Corp.,
533 U.S. 218 (2001). . . . . passim

United States v. Mistretta,
488 U.S. 361 (1989). 38

Vt. Yankee Nuclear Power Corp. v. NRDS,
435 U.S. 519 (1978). 20

Williamson County Regional Planning Commission v. Hamilton Bank of Johnson City,
473 U.S. 172 (1985). 33

CONSTITUTION

U.S. Const. Am. V. 32

U.S. Const. art. I, § 8, cl. 8. 37

STATUTES

5 U.S.C. § 552. 23

5 U.S.C. § 553. 4

5 U.S.C. § 553(b). 4, 43

5 U.S.C. § 553(b)(3). 43

5 U.S.C. §§ 601-612. 46

5 U.S.C. § 706. . . . . 25, 33, 37

5 U.S.C. § 706(2)(A). 18, 21, 28

7 U.S.C. § 136. 29

35 U.S.C. § 2. 11

35 U.S.C. § 2(b)(2). . . . . passim

35 U.S.C. § 2(b)(2)(A). 3, 7

35 U.S.C. § 2(b)(2)(B). 4

35 U.S.C. § 2(b)(2)(C) 3

35 U.S.C. § 2(b)(2)(D). 3, 7

35 U.S.C. § 41. 17

35 U.S.C. § 101. 18

35 U.S.C. § 102. . . . . 6, 18

35 U.S.C. § 103. . . . . 6, 18

35 U.S.C. § 111. 18

35 U.S.C. § 112. . . . . passim

35 U.S.C. § 120. . . . . passim

35 U.S.C. § 121. . . . . 9, 19

35 U.S.C. § 122. 19

35 U.S.C. § 122(b)(2)(B)(i). 28

35 U.S.C. § 131. . . . . 13, 17, 18

35 U.S.C. § 132. 6

35 U.S.C. § 132(a). 13, 41

35 U.S.C. § 132(b). 12, 13

35 U.S.C. § 151. 18

35 U.S.C. § 154(d). 30, 33

35 U.S.C. § 154(d)(1). 30

35 U.S.C. § 154(d)(2). 30

35 U.S.C. § 171. 15

35 U.S.C. § 200. 18

35 U.S.C. § 251. 9

35 U.S.C. § 261. . . . . 30, 33

44 U.S.C. § 3516. 23

49 U.S.C. §§ 32901-19. 21

LEGISLATIVE MATERIALS

American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1),
113 Stat. 1501 (1999).. 13

S. Rep. 82-1979 (1952), reprinted at 1952 U.S.C.C.A.N. 2394, 2400. 10

RULES

Local Civ. R. 56(B). 36

Fed. Cir. R. 1(f). 5

Fed. R. Civ. P. 37(b)(2)(A)(v). 14

Fed. R. Civ. P. 41(b). 14

Sup. Ct. R. 39.8. 5

EXECUTIVE ORDERS

Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993). 24, 48, 49

REGULATIONS

37 C.F.R. § 1.105 (2006). 14

37 C.F.R. § 1.105(c) (2006).. 14

37 C.F.R. § 1.183 (2006). 37

37 C.F.R. § 10.18(b)(2)(i) (2006). 31

37 C.F.R. § 10.77(b) (2006).. 31

FEDERAL REGISTER

Changes to Implement the Patent Business Goals, 63 Fed. Reg. 53497, 53506-08 (Oct. 15, 1998). 43

Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. 46716 (Aug. 21, 2007). . . . . passim

Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61 (Jan. 3, 2006). 25, 43

Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48 (Jan. 3, 2006). 45

MANUAL OF PATENT EXAMINATION PROCEDURE

MPEP § 714(i). 35, 37

MPEP § 706.07. 45

MISCELLANEOUS

Archie R. McCrady, PATENT OFFICE PRACTICE 115 (1928) 19

Philippe Signore, The New Provisional Rights Provision, 82 J. Pat. & Trademark Off. Soc'y, 742, 745 (2000) 30

Thomas Schneck, The Duty to Search, 87 J. Pat. & Trademark Off. Soc'y 689 (2006). 31

TABLE OF ABBREVIATIONS FOR CITATIONS TO COURT FILINGS

Abbreviation	Filing
GSK Am. Compl.	Verified Amended Complaint, Dkt. No. 5, 1:07cv1008
GSK Opp.	GlaxoSmithKline's Opposition to Defendants' Motion for Summary Judgment Against the "GlaxoSmithKline" Plaintiffs, Dkt. No. 252, 1:07cv846
Polestar Br.	Brief of *Amici Curiae* Polestar Capital & Norseman Group in Support of Plaintiffs, Dkt. No. 173, 1:07cv846
Strike Mem.	Memorandum in Support of Defendants' Motion to Strike, Dkt. No. 250, 1:07cv846
Tafas Am. Compl.	First Amended Complaint for Declaratory and Injunctive Relief and Petition for Review of Rulemaking, Dkt. No. 14, 1:07cv846
Tafas Opp.	Plaintiff Triantafyllos Tafas' Memorandum of Law In Opposition to Defendants' Summary Judgment Motion, Dkt. No. 253, 1:07cv846
USPTO GSK Opp.	Defendants' Memorandum in Opposition to GlaxoSmithKline's Motion for Summary Judgement, Dkt. No. 246, 1:07cv846
USPTO Mem.	Memorandum in Support of Defendants' Motion for Summary Judgment, Dkt. No. 127, 1:07cv846
USPTO Tafas Opp.	Defendants' Memorandum in Opposition to Plaintiff Triantafyllos Tafas's Motion for Summary Judgment, Dkt. No. 247, 1:07cv846

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively "USPTO" or "Office") respectfully submit this memorandum in support of their motions for summary judgment against Plaintiff Triantafyllos Tafas ("Tafas") and the GlaxoSmithKline Plaintiffs ("GSK"), and in rebuttal to the Plaintiffs' memoranda in opposition to the USPTO's summary judgment motions.[1] See Pl. Triantafyllos Tafas' Mem. of L. In Opp. to Defs. Summ. J. Mot., Dkt. No. 253 ("Tafas Opp."); GlaxoSmithKline's Opp. to Defs. Mot. for Summ. J. Against the "GlaxoSmithKline" Pls., Dkt. No. 252 ("GSK Opp.").

INTRODUCTION

The Final Rules concerning claims and continuations practice represent a lawful, careful, and critically important exercise of the USPTO's expressly-delegated rulemaking authority.[2] The product of more than two years of study, the rules reflect the USPTO's commitment to keeping pace with a burgeoning patent system by enacting procedural reforms that are tailored to redress the most pressing problems facing the agency.

Unable to show that the Final Rules are unlawful, GSK resorts to mischaracterizing them as "mechanical limits" and "caps," and claiming that the USPTO has conceded points that it has always contested. Tafas similarly mischaracterizes the Final Rules, but also uses his opposition memorandum to impermissibly "adopt" arguments of *amici* and to set forth facts about himself and his business that he conceded in his summary judgment motion were irrelevant to a facial challenge to the rules. Both plaintiffs use their opposition memoranda to try to enlarge the claims in their amended complaints – efforts this Court should see through and disallow.[3]

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[1] Rather than responding to Plaintiffs' briefs in two separate memoranda of up to twenty-five pages each, the USPTO has combined its response into a single brief of fifty pages. See Dkt. No. 102, Am. Order, Dec. 5, 2007.

[2] Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. 46716 (Aug. 21, 2007) ("Final Rules") (Mem. in Supp. of Defs. Mots. for Summ. J. ("USPTO Mem."), Dkt. No. 127, Ex. 1).

In the end, Plaintiffs fail to show that their desire to stave off change justifies enjoining lawful rules. The Court should grant the USPTO's summary judgment motions and allow the Final Rules to take effect.

ARGUMENT

I. THE FINAL RULES ARE CONSISTENT WITH THE PATENT ACT

A. The Final Rules Were Promulgated Pursuant to Expressly Delegated Rulemaking Authority and Are Thus Eligible for Chevron Deference

Plaintiffs admit, as they must, that an agency's rules are entitled to Chevron deference when they are promulgated pursuant to an express delegation of rulemaking authority. See GSK Opp. at 5-6; Tafas Opp. at 12; Chevron USA, Inc. v. NRDC, Inc., 467 U.S. 837 (1984). Indeed, Plaintiffs' own cases leave no doubt that a Congressional delegation of rulemaking authority is the touchstone of Chevron deference. Tafas Opp. at 12 (citing United States v. Mead Corp., 533 U.S. 218, 226-27 (2001) (holding that regulations "qualif[y] for Chevron deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law")); GSK Opp. at 5 (citing Pesquera Mares Australes Ltda. v. United States, 266 F.3d 1372, 1380-81 (Fed. Cir. 2001) (quoting Mead, 533 U.S. at 226-27); Atchison, Topeka & Santa Fe Ry. Co. v. Pena, 44 F.3d 437, 441 (7th Cir. 1994) (en banc)).

As the USPTO has shown, 35 U.S.C. § 2(b)(2) expressly delegates to the Office authority to enact the Final Rules. Plaintiffs offer no reason why Final Rules 78 and 114, which address how many times applicants may appear before the agency, revising old applications, before they must submit a petition to justify further continuing applications and requests for continued examination ("RCE"), do not fall within the plain language of § 2(b)(2). They clearly do. These rules "govern the conduct of proceedings in the Office," id. § 2(b)(2)(A), by focusing, "facilitat[ing] and expedit[ing] the processing of patent applications," id. § 2(b)(2)(C). By curtailing delays in prosecution, they further "govern the . . . conduct of agents, attorneys, or other persons representing applicants or other parties before the Office." Id. at § 2(b)(2)(D). Final Rules 75 and 265, which address the information that applicants must provide the Office when they submit applications that contain burdensome numbers of claims, similarly fall within the plain language of § 2(b)(2)(A) and (C) and are thus entitled to Chevron deference.[4]

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[3] Compare, e.g., Tafas Am. Compl. ¶ 6 (asking the Court to "prevent Defendants from implementing sections 1.75, 1.78, 1.114, 1.265 and 1.704"), with Tafas Opp. at 1 (asking the Court to "enjoin the USPTO from implementing sections 1.75, 1.78, 1.104, 1.105, 1.110, 1.114, 1.142, 1.265 and 1.704"). The additional rules that Tafas now asks to have enjoined are not properly before the Court.

GSK criticizes the USPTO for not citing Adams Fruit Co. v. Barrett, 494 U.S. 638 (1990), in its opening summary judgment brief, but that case is inapposite. GSK Opp. at 7. As the USPTO explained in responding to GSK's summary judgment motion, see Defs. Mem. in Opp. to GlaxoSmithKline's Mot. for Summ. J. ("USPTO GSK Opp."), Dkt. No. 246, at 7, the Supreme Court declined to defer to the Department of Labor in Adams Fruit because the agency had attempted to regulate "the scope of judicial power" by determining when private rights of action existed in federal court. Id. at 650. Here, by contrast, the USPTO has enacted rules to govern the proceedings in its own Office, not the federal courts, and Congress has expressly delegated it the authority to do so. See 35 U.S.C. § 2(b)(2). Moreover, unlike the USPTO, the

[4] Tafas argues that neither "35 U.S.C. § 2(b)(2), nor any other statutory provision, expressly or impliedly authorizes the USPTO to make rules that 'carry the force and effect of law.'" Tafas Opp. at 13. This is plainly incorrect. Although the parties may dispute whether the Final Rules fall within the parameters of the § 2(b)(2) powers, it cannot be disputed that § 2(b)(2) authorizes the USPTO to promulgate some regulations that have the force and effect of law. See, e.g., Norton v. Curtiss, 433 F.2d 779, 791 (C.C.P.A. 1970) ("We have long held that [regulations promulgated pursuant to § 2(b)(2)], when not inconsistent with the statutes, have the force and effect of law."). It is unclear why Congress would delegate rulemaking authority to an agency if not to make rules that have the force and effect of law.

Department of Labor did not utilize notice and comment rulemaking. GSK's own case explains that where an agency "has adopted a regulation by notice-and-comment rulemaking pursuant to the Administrative Procedure Act (5 U.S.C. § 553), the Chevron standard, of course, applies." Pesquera Mares Australes, 266 F.3d at 1379 (citing Mead, 533 U.S. at 230). Congress has expressly delegated to the USPTO authority to promulgate rules using APA notice-and-comment procedures. See 35 U.S.C. § 2(b)(2)(B) (authorizing the USPTO to promulgate regulations "in accordance with section 553 of title 5"). Neither Plaintiff explains why § 2(b)(2)(B) does not further evince Congress's intent for the Office's rules to receive Chevron deference.

Despite Plaintiffs' acknowledgment that Congressional delegation is the touchstone of Chevron deference, they nevertheless persist in focusing on an irrelevant dichotomy between "substantive" and "procedural" rulemaking.[5] The Supreme Court has never found Chevron deference to turn on this dichotomy, and the USPTO has already explained why the discussion of substantive rulemaking authority in Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), should not control this case. See USPTO Mem. at 17-18 (explaining that Merck is distinguishable on its facts, and that it did not authoritatively interpret the scope of § 2(b)(2) under Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 982 (2005)).[6]

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[5] In referring to a "false dichotomy" in its opening brief, the USPTO was not suggesting that the distinction between "substantive" and "procedural" rules is never a meaningful one. GSK Opp. at 11 (quoting USPTO Mem. at. 17). The APA itself draws such a distinction in 5 U.S.C. § 553(b) to determine when notice and comment rulemaking is required. Instead, the USPTO was simply explaining that such a dichotomy is irrelevant to the question of Chevron deference, which the Supreme Court has never found to turn on whether rules are substantive or procedural.

[6] GSK's attempt to explain in a footnote why Brand X is inapplicable is unavailing. GSK Opp. at 6-7 n. 2. GSK first argues that "Brand X only applies if an agency is entitled to Chevron deference," but as the USPTO has demonstrated, it is so entitled. Id. GSK's remaining arguments – that 35 U.S.C. § 120 is purportedly unambiguous and that the doctrine of laches should be used sparingly – are irrelevant to whether the Federal Circuit's interpretation of § 2(b)(2) is controlling. Furthermore, the language from Lechmere, Inc. v. NLRB, 502 U.S. 527

Even if the dichotomy were relevant, however, the Final Rules are procedural. Like other procedural rules, the Final Rules "'alter the manner in which parties present themselves or their viewpoints to the agency,'" but do not alter applicants' rights. Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (quoting Batterton v. Marshall, 648 F.2d 694, 707 (D.C. Cir. 1980)); see also JEM Broadcasting Co. v. FCC, 22 F.3d 320, 327 (D.C. Cir. 1994) (holding that rules were procedural where they established a cut-off date by which applications had to be filed, causing some applicants not to be able to re-file applications); USPTO GSK Opp. at 8-10. Plaintiffs apparently concede that Final Rules 78 and 114 are indistinguishable from rules of judicial procedure that address repetitive and vexatious filings, as they offer no grounds for distinction. USPTO Mem. at 19 (citing Fed. Cir. R. 1(f); Sup. Ct. R. 39.8).

GSK argues that the Final Rules are substantive because they allegedly "limit continuing applications, RCEs, and claims" in a way that "affect[s] GSK's substantive rights." GSK Opp. at 4. GSK's argument proceeds from two false premises. First, GSK mischaracterizes the Final Rules. Final Rules 78 and 114 do not impose a mechanical limit on the number of continuing applications or RCEs an applicant may file, but rather put reasonable conditions on such filings. In its opposition to GSK's memorandum, the USPTO discussed the flexible, case-by-case analysis that the agency will undertake to determine whether a petition under Final Rules 78 or 114 is meritorious. See USPTO GSK Opp. at 15-17. Similarly, Final Rules 75 and 265 do not impose a cap on claims. Applicants can submit as many claims as they want as long as they provide information in support of unusually large applications containing more than five

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(1992), that GSK quotes simply stands for the principle, articulated again in Brand X, that where courts have determined a statute's unambiguous meaning, an agency's rules may not deviate from that interpretation. GSK Opp. at 6; Brand X, 545 U.S. at 982; id. at 984 (discussing Lechmere). Because the Federal Circuit has not interpreted any of the relevant Patent Act provisions as to unambiguously preclude the Final Rules, Lechmere is irrelevant.

independent or twenty-five total claims.[7]

Second, the Final Rules do not impinge on any substantive "rights" GSK purports to have under the Patent Act. GSK Opp. at 5. GSK argues that the Final Rules implicate 35 U.S.C. §§ 102 and 103, two of the sections that establish substantive eligibility criteria for patents, but they do not. Claims that would have met the novelty and non-obviousness criteria of these sections before the Final Rules will still meet these criteria under the Final Rules. Because the Final Rules do not seek to interpret provisions like §§ 102 and 103 that define eligibility for a patent, they are not substantive rules under Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 930 (Fed. Cir. 1991), or Chrysler Corp. v. Brown, 441 U.S. 281 (1979).[8] GSK Opp. at 4.

Further, as discussed later in this brief, neither § 120 nor § 132 unambiguously establishes a "right" to file unlimited continuation applications or RCEs, no matter how delayed those applications may be or how much they burden the agency. See infra, Parts I.B, I.C. Nor do Final Rules 75 and 265 bar applicants from submitting "one or more claims" under § 112. Id., Part I.D. As noted above, applicants may submit as many claims as they want, even when they exceed 5/25 claims; they simply must submit information about their claims to assist in examination. The Final Rules thus are not substantive even under GSK's broad definition.

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[7] Tafas's analogy – that "the USPTO's approach would be akin to the manager of an amusement park seeking to reduce lines for rides by not admitting anyone to the park" – is flawed for the same reasons. Tafas Opp. at 15. The USPTO is clearly letting people into the park. Final Rules 78 and 114 simply prevent a patron from riding the same ride more than four times without good reason when his repeated rides are preventing others from taking a turn.

[8] In fact, Chrysler Corp. only underscores the procedural nature of the Final Rules. There, the Supreme Court looked to Morton v. Ruiz, 415 U.S. 199 (1974), for its definition of a substantive rule. Chrysler Corp., 441 U.S. at 302. The Morton Court only found the rules at issue to be substantive because the Bureau of Indian Affairs had changed an "extremely significant eligibility requirement" for American Indians who received benefits from the government; for the first time, beneficiaries had to live on reservations. Morton, 415 U.S. at 236. The USPTO has not altered the eligibility requirements for receiving a patent (e.g., novelty, non-obviousness), but only the procedures for applying for one.

Because the Final Rules fall within the plain language of § 2(b)(2), Plaintiffs can point to no meaningful basis for distinguishing them from the rules in Lacavera v. Dudas, 441 F.3d 1380 (Fed. Cir. 2006), Stevens v. Tamai, 366 F.3d 1325 (Fed. Cir. 2004), and Centigram Commc'ns Corp. v. Lehman, 862 F. Supp. 113 (E.D. Va. 1994), which the Federal Circuit and this Court implicitly or explicitly accorded Chevron deference.[9] In Lacavera, the Federal Circuit emphasized that, "[u]nder 35 U.S.C. § 2(b)(2), the PTO has broad authority to govern the conduct of proceedings before it and to govern the recognition and conduct of attorneys." 441 F.3d at 1382-83. Citing Mead and Chevron, the court held that "[b]ecause the PTO is specifically charged with administering this statute, we analyze a challenge to the statutory authority of its regulations under the Chevron framework." Id. The same is true here.

Finally, GSK errs in suggesting that if the Court declines to afford the Final Rules Chevron deference, it should afford them no deference at all. GSK's own cases show that the USPTO is at least entitled to deference under Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).[10] Merck, 80 F.3d at 1550 (affording Skidmore deference); Atchison, Topeka, 44 F.3d at 442 ("That is not to say that interpretive rules, while undeserving of substantial deference under Chevron, do not warrant any deference from a reviewing court."); see also Cathedral Candle Co. v. U.S. Intern. Trade Comm'n, 400 F.3d 1352, 1365 (Fed. Cir. 2005) ("Even if Chevron deference does not apply, an agency's construction of a statute that it is charged with administering is still subject to some deference under the standard set forth by the Supreme Court in Skidmore . . ."). The additional cases GSK cites are not to the contrary.[11] GSK Opp. at 9.

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[9] Tafas attempts to distinguish Lacavera by arguing that it turned solely on the USPTO's exercise of authority under § 2(b)(2)(D), Tafas Opp. at 16, but the Federal Circuit made clear in Lacavera that it was addressing both sources of authority. See Lacavera, 441 F.3d at 1383 ("[T]he PTO has broad authority to govern the conduct of proceedings before it and to govern the recognition and conduct of attorneys."). Moreover, the USPTO has relied on both sources of authority in promulgating the Final Rules. See USPTO Mem. at 14-15. Stevens, too, expressly turned on the USPTO's exercise of its § 2(b)(2)(A) power. Stevens, 366 F.3d at 1333.

[10] Tafas concedes that to the extent the Final Rules are "interpretative or procedural," the USPTO should be accorded Skidmore deference. Tafas Opp. at 13.

B. Final Rule 78 Places Reasonable Conditions on the Filing of Continuing Applications, Consistent with Section 120 of the Patent Act

As the USPTO has explained, 35 U.S.C. § 120 creates a mechanism by which a later-filed application may, under certain conditions, receive the priority date of a pending prior-filed application. See USPTO Mem. at 21; USPTO GSK Opp. at 11. Section 120 does not provide, as GSK contends, that "the PTO shall (*i.e.* must) accord" every continuing application the priority date of a prior-filed application, no matter how repetitious or vexatious the application may be. GSK Opp. at 12. In fact, § 120 does not speak in terms of "the PTO" at all. See 35 U.S.C. § 120 ("An application . . . shall have the same effect . . .") (emphasis added). Section 120 is simply silent as to how many times the USPTO must process an applicant's recycled continuing applications. Consequently, the Office may exercise its § 2(b)(2) authority to promulgate reasonable regulations.[12] Chevron, 467 U.S. at 842-43.

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[11] In FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132-33 (2000), the Supreme Court applied the Chevron framework, but held that it could not afford Chevron deference because the statute unambiguously precluded the FDA's interpretation – that is, the regulation failed at Chevron Step One. It is entirely different to utilize the Chevron framework but find that a statute unambiguously precludes a regulation at Chevron Step One, as occurred in Brown & Williamson and is the question to which the USPTO turns next, than to refuse to utilize the Chevron framework at all, as GSK asks this Court to do. The other cases GSK cites either are no different from Brown & Williamson, see Am. Bar Ass'n v. FTC, 430 F.3d 457, 468-70 (D.C. Cir. 2005) (utilizing Chevron framework but finding that regulation failed at Chevron Step One), involve attempts by agencies to interpret statutes that other entities are empowered to administer, Sac & Fox Nation of Mo. v. Norton, 240 F.3d 1250, 1265-66 (10th Cir. 2001), or involve an interpretation in a single letter that, unlike the Final Rules, was "made without any degree of deliberation, thoughtful consideration or comments from the public," N.Y. State Bar Ass'n v. FTC, 276 F. Supp. 2d 110, 139 (D.D.C. 2003).

[12] By contrast, in Railway Labor Executives Assocation v. National Mediation Board, 29 F.3d 655, 671 (D.C. Cir. 1994) (en banc), cited by GSK, the court held that the text, structure, and legislative history of the statute under review all pointed toward an unambiguous meaning that foreclosed proceeding past Chevron Step One. Here, however, the text does not speak to the

Plaintiffs fail to respond to the USPTO's core arguments regarding the language of § 120. They fail, for example, to explain why the USPTO's interpretation of the phrase "shall have the same effect as" is incorrect, or to counter the history the USPTO cites in support of its argument. See USPTO Mem. at 21-22 (citing Godfrey v. Eames, 68 U.S. 317, 324 (1863)). Plaintiffs also lack any response to the argument that Final Rule 78 merely puts reasonable conditions on when continuation applications may be considered properly "filed" under § 120. USPTO Mem. at 22. Their silence on these central issues speaks volumes.

Plaintiffs also offer no evidence that § 120 unambiguously precludes Final Rule 78. To the contrary, their reading of § 120 brings that section into tension with other provisions of the Patent Act, including §§ 112, 121 and 251. See USPTO Mem. at 22-23. GSK objects that "the PTO has applied these sections without any conflict for decades." GSK Opp. at 13. GSK fails to appreciate, however, that the use of continuations practice has changed dramatically over the past several decades in a way that undermines the overall scheme of the Patent Act. "Continued examination filings, other than divisional applications, as a percentage of overall filings, has increased from about 11.4 percent in fiscal year 1980, to about 18.9 percent in fiscal year 1990, to 21.9 percent in fiscal year 2000, to 29.4 percent in fiscal year 2006." 72 Fed. Reg. at 46718. In particular, the number of second and higher continuing applications has exploded, tripling from fewer than 15,000 per year in 1997 to more than 45,000 per year in 2006. A05015 (Ex. 1). Likewise, the number of third and higher continuing applications grew from fewer than 6,500 per year in 1997 to more than 18,000 per year in 2006. Id. Final Rule 78 merely interprets § 120 in a way that allows it to peaceably coexist with §§ 112, 121 and 251 rather than eclipsing those sections. See, e.g., 72 Fed. Reg. at 46754, 46760 (addressing relationship of Final Rules to § 251

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question at issue, and Plaintiffs cite no authoritative legislative history or structural arguments that would foreclose the USPTO's reading of § 120.

reissue provision); id. at 46719, 46754, 46768 (discussing relationship of Final Rules to § 112).

Turning to legislative history, Tafas cites a single speech by one of the drafters of the Patent Act of 1952, Hon. Giles S. Rich, which Tafas contends shows that § 120 was intended to allow limitless continuation applications. Tafas Opp. at 19. The speech is far more qualified than he suggests.[13] Moreover, more authoritative legislative history of the Patent Act of 1952 is silent on this point. See S. Rep. 82-1979 (1952), reprinted at 1952 U.S.C.C.A.N. 2394, 2400. Further, even if one drafter held this view, another principal drafter, P.J. Federico,[14] clearly did not. Examiner-in-Chief Federico authored the decision for the Board of Patent Appeals ("Board") in Ex Parte Henriksen, 154 U.S.P.Q. 53 (Bd. of Pat. Appeals 1966) (Federico, Examiner in Chief), which condoned an absolute limit of two continuation applications. Where two of the principal drafters of a statute cannot agree, it is certainly fair to say that "the statute is silent or ambiguous with respect to the specific issue." Chevron, 467 U.S. at 843.

Plaintiffs cite no case law that unambiguously precludes Final Rule 78.[15] The Office specifically addressed in its Federal Register notice the language of Kingsdown Medical

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[13] Tafas distorts Judge Rich's discussion of § 120 by making liberal use of ellipses. The first sentence of Rich's comments on § 120 supports the USPTO's construction of that section, and the remainder attests to its lack of clarity: "Section 120 gives co-pending applications the benefit of the filing date of a parent case, but only if there is in the later application a specific reference to the earlier one. Some people have questioned whether this would apply to more than one succession, one application in succession to one parent; I think that, on careful reading, you will agree that the number of generations of the lineage is unlimited." Address of Giles S. Rich to the New York Patent Law Ass'n, Nov. 6, 1952, reprinted in 75 J. Pat. & Trademark Off. Soc'y 3, 13-14 (1993) (emphases added).

[14] See Paulik v. Rizkalla, 760 F.2d 1270, 1277 (Fed. Cir. 1985) (Rich, J. concurring) (identifying Federico as "the key person" in the drafting of the Patent Act of 1952).

[15] The USPTO has already addressed In re Henriksen, 399 F.2d 253 (C.C.P.A. 1968), In re Hogan, 559 F.2d 595 (C.C.P.A. 1977), Ex Parte Hull, 191 U.S.P.Q. 157 (Pat. & Trademark Office Bd. App. 1975), and Ricoh Co. Ltd. v. Nashua Corp., 1999 WL 88969 (Fed. Cir. 1999) (unpublished), in its prior briefs. See USPTO GSK Opp. at 11-12 & n.7; USPTO Mem. at 24-25.

Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988), that both GSK and Tafas quote. Tafas Opp. at 20; GSK Opp. at 13; 72 Fed. Reg. at 46762. As the USPTO explained there, the Federal Circuit merely noted in Kingsdown that there is nothing wrong with filing a patent application or amending one's claims for the purpose of keeping a competitor's products from the market. 863 F.2d at 874. Final Rule 78 does not prevent an applicant from doing so; an applicant may file an initial application and two continuations for this purpose before it even needs to file a petition. 72 Fed. Reg. at 46839; 37 C.F.R. § 1.78(d)(1)(vi). The Federal Circuit did not say that § 120 confers an unambiguous right to file an unlimited number of continuation applications for this purpose, or to deliberately delay ending prosecution at the examiner level in order to await a competitor's product. See Brand X, 545 U.S. at 982.

As the USPTO also made clear in the Federal Register notice, Final Rule 78 is not an effort to codify the doctrine of prosecution laches. 72 Fed. Reg. at 46720. Although In re Bogese, 303 F.3d 1362 (2002), arose in the context of that doctrine, the Federal Circuit confirmed that the USPTO's "authority to sanction undue delay is even broader than the authority of a district court to hold a patent unenforceable" on laches grounds. Id. at 1367 (emphasis added). In fact, "[t]he PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications." Id. at 1368 (citing 35 U.S.C. § 2). Final Rule 78 is an exercise of the USPTO's rulemaking authority under 35 U.S.C. § 2(b)(2), not an attempt to rely on an equitable doctrine.

Plaintiffs thus err in attempting to confine the Office's rulemaking authority using cases that define the parameters of prosecution laches. See, e.g., Symbol Techs., Inc. v. Lemelson Med., Educ., & Res. Found., LP, 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("Symbol IV"). The Federal Circuit indeed stated in Symbol IV that "[t]here are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches" and provided examples of such legitimate grounds. Id. (emphasis added). But Final Rule 78 does not aim to enforce the doctrine of prosecution laches. Moreover, even Symbol IV recognized that while there may be legitimate grounds to once, or perhaps even twice, "refile an application," such refiling may not be "unduly successive or repetitive." 422 F.3d at 1385.

Final Rule 78 is a reasonable attempt to rein in unduly successive and repetitive continuing applications. See 72 Fed. Reg. at 46719. The rule does not create a "hard limit" on continuing applications. GSK Opp. at 12-13. The USPTO has explained at length the flexible, "case-by-case" analysis that it will undertake in evaluating petitions.[16] USPTO GSK Opp. at 16-17 (citing 72 Fed. Reg. at 46770-79). The USPTO has also identified at least four examples of when the Office expects to grant petitions. Id. (citing 72 Fed. Reg. at 46773-76); cf. GSK Opp. at 13 n. 9 (incorrectly stating that "PTO fails to identify a single set of circumstances that would satisfy the standard"). To the extent that Plaintiffs are concerned that any specific application of Final Rule 78 will harm them, they may later challenge the denial of a petition in federal court. See 72 Fed. Reg. at 46779. The Court cannot, on this facial challenge, tolerate bald speculation about how the USPTO may someday effectuate a rule that is to be implemented on a "case-by-case" basis. See USPTO GSK Opp. at 15-16. On its face, Final Rule 78 must stand.

C. Final Rule 114 Comports With Section 132

Plaintiffs remarkably deduce from the sentence, "[t]he Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant" that applicants may submit unlimited requests for continued examination ("RCE"). 35 U.S.C. § 132(b); GSK Opp. at 17; Tafas Opp. at 22. The plain text of this section does not support their reading. The word "shall" simply directs the Office to "prescribe regulations," while the phrase "to provide for the continued examination of applications" specifies the focus of those regulations. Because Section 132(b) is silent on the number of RCEs that applicants may file, the USPTO may exercise its authority under both §2(b)(2) and § 132(b) itself to prescribe reasonable regulations regarding the number of times an applicant may prolong prosecution at the examiner level rather than appealing a rejection to the Board. Chevron, 467 U.S. at 842-43.

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[16] The Bogese Court did not state, as GSK claims, that "the PTO lacks the ability to impose 'a mechanical rule based on a misconstruction of the statutory requirements,'" but even if it had, Final Rule 78 does not establish a "mechanical rule" or misconstrue § 120. GSK Opp. at 16 (quoting Bogese, 303 F.3d at 1368 n.6).

Final Rule 114 is such a reasonable regulation, working in concert with Final Rule 78 to allow an applicant two continuing applications and one RCE in each application family, before filing a petition and making a showing to justify further filing (the "2+1 Rule"). GSK argues for the first time that Final Rule 114 may not operate at the level of the application family, even though Final Rule 78 does the same. GSK Opp. at 17-18. Cobbling together disparate text, GSK "read[s] together" §§ 131, 132(a), and 132(b) to conclude that the statutes "require the PTO to examine applications and provide for the continued examination of applications—not each application family."[17] Id. at 18. But none of those provisions – read together or alone – unambiguously requires the USPTO to accept an RCE for each and every application in a string of virtually indistinguishable continuation applications.[18] Final Rule 114 sets reasonable conditions on the filing of more than one RCE in an application family so that applicants will no longer be able to force the Office to re-examine – *ad infinitim* – the same rejected applications, while new applications languish in the backlog.[19]

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[17] GSK also throws into the mix language from the unremarkable effective date provision of the American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. 1501 (1999), but the USPTO has already addressed why this provision has no bearing on the issue. See USPTO GSK Opp. at 14-15. Tafas reiterates GSK's error. Tafas Opp. at 22.

[18] Indeed, § 131 does not concern RCEs at all. It simply provides for the examination of applications generally. See 35 U.S.C. § 131.

D. Final Rules 75 and 265 Are Consistent With Section 112

As GSK well knows, the USPTO is not arguing that "it may limit the number of claims an applicant may submit." GSK Opp. at 19. Final Rules 75 and 265 allow applicants to submit as many claims as they want; they must, however, provide information to assist in examination if they wish to submit more than five independent or twenty-five dependent claims (the "5/25 Rule"). These rules thus could not conflict with 35 U.S.C. § 112, ¶ 2, as GSK alleges, because applicants may still submit "one or more claims."[20]

GSK fails to meaningfully distinguish Application of Rubinfield, 270 F.2d 391, 395 (C.C.P.A. 1959), where the Court of Customs and Patent Appeals ("C.C.P.A.") held (not stated in *dicta*, as GSK claims) that even limiting design patents to only one claim was consistent with

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[19] GSK improperly introduces a new "arbitrary and capricious" claim in a footnote to its § 132 argument, contending that the USPTO should have to explain why it has allegedly departed from the "prior construction of" § 132 embodied in rules that it promulgated in 2000. GSK Opp. at 19 n.12. Even if the Court considers this new claim, the USPTO has never construed the statute in the manner GSK ascribes to it. As previously explained, the USPTO did not state in 2000 that it could not place conditions on the filings of RCEs; rather, it simply stated that, as a descriptive matter, its prior rules were not doing so. USPTO GSK Opp. at 15. The statute clearly allows the USPTO to enact Final Rule 114, and, consequently, no further explanation is required. In any event, the USPTO has amply explained why it is now changing its rule.

[20] Amidst its discussion of § 112, GSK returns to the question of whether Final Rules 75 and 265 are procedural or substantive. GSK Opp. at 20. Although the issue is irrelevant for the reasons already discussed, it bears noting that the rules are not substantive merely because an applicant's refusal to submit an ESD will lead to the abandonment of an application. The failure to comply with countless other procedural rules has the same consequence. For example, in Star Fruits S.N.C. v. United States, 393 F.3d 1277 (Fed. Cir. 2005), the Federal Circuit upheld 37 C.F.R. § 1.105 (2006), as a proper exercise of the USPTO's § 2(b)(2) authority, even though failure to submit the information required under that rule could similarly lead to abandonment of an application. See 37 C.F.R. § 1.105(c) (2006). Similarly, a civil plaintiff's failure to file a discovery plan could lead to dismissal of his lawsuit, see Fed. R. Civ. P. 37(b)(2)(A)(v), 41(b), but that does not render the requirement of filing a discovery plan substantive.

§ 112, ¶ 2. GSK Opp. at 21.[21] That, of course, was a far more restrictive measure than requiring applicants to provide information when they submit more than 5/25 claims. Contrary to GSK's contention, Rubinfield does not rest on a "since-discarded analytical framework regarding deference." Id.; see id. n. 14. Adams Fruit could not have overruled Rubinfield's deferential approach when Adams Fruit is inapposite, and a later panel of the Federal Circuit in Merck would not have been empowered to overrule an earlier decision of the C.C.P.A. See South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc) (adopting C.C.P.A. decisions as binding precedent of the Federal Circuit). If anything, Chevron and Mead have only confirmed the correctness of the C.C.P.A.'s approach in Rubinfield.

Moreover, while there are some differences between design and utility patents, any such differences are irrelevant to the present inquiry, which is whether § 112, ¶ 2 unambiguously precludes Final Rules 75 and 265. 35 U.S.C. § 171, which governs design patents, states that "[t]he provisions of this title relating to patents for inventions shall apply to patents for designs, except as otherwise provided." However, nothing "otherwise provides" that § 112, ¶ 2 is inapplicable to design patents, or means something different when applied to them. To the contrary, the Federal Circuit has recognized that § 112 applies equally to design patents. See In re Daniels, 144 F.3d 1452, 1456 (Fed. Cir. 1998) ("Although linguists distinguish between a drawing and a writing, the drawings of the design patent are viewed in terms of the 'written description' requirement of § 112."). Rubinfield likewise recognized that § 112, ¶ 2 applied to design patents but refused to hold that the section's reference to "one or more claims" required the USPTO to allow more than one claim in such patents. 270 F.2d. at 395. Here, GSK argues for an even more erroneous interpretation of § 112, ¶ 2 – one that would read this section as requiring the Office to allow applicants to submit as many claims as they want without any information about them. Section 112 does not suggest, much less unambiguously compel, such a reading, and the USPTO's reasonable rules must therefore be upheld.[22]

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[21] The USPTO need not address again why GSK's reliance on cases involving rejections for "undue multiplicity" are inapt. See USPTO GSK Opp. at 18-19 (discussing cases cited at GSK Opp. at 20-21 & n. 20).

E. Tafas's Ancillary Patent Act Claims Lack Merit

Tafas faults the USPTO for either "misapprehend[ing]" or "mischaracteriz[ing]" the Patent Act claims he raised in single-spaced sub-paragraphs (a) through (n) of paragraph 56 of his First Amended Complaint. Defs. Mem. in Opp. to Pl. Triantafyllos Tafas's Mot. for Summ. J. ("USPTO Tafas Opp."), Dkt. No. 247, at 25. The USPTO labored to untangle those paragraphs and rebutted the claims it could discern in its opening summary judgment brief. USPTO Mem. at 29-33. To the extent Tafas raised additional claims in his summary judgment motion, the USPTO thoroughly addressed each claim in its opposition memorandum. USPTO Tafas Opp. at 1-13. Tafas's own opposition memorandum adds little to his summary judgment motion, and the USPTO thus stands on its previous discussion of the majority of those ancillary claims.[23] See id. at 12-14 (addressing Tafas's claim regarding "first action final rejection" practice, which the Final Rules have not changed, Tafas Opp. at 22-23); id. at 10-12 (explaining why Final Rule 75 does not alter statutory definitions under 35 U.S.C. §§ 41 or 112, Tafas Opp. at 25); id. at 6-8 (explaining why Final Rule 78(d) is consistent with 35 U.S.C. § 121 in its treatment of "voluntary divisionals," Tafas Opp. at 26)[24]; see also id. at 38-41 (addressing Tafas's newly-minted claims under international treaties, which he improperly conflates with claims under the Patent Act, Tafas Opp. at 25).

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[22] GSK argues for the first time in its opposition brief that Final Rule 265 unlawfully creates a new requirement to search prior art and shifts the burden of prosecution from the USPTO to the applicant. GSK Opp. at 22-24. The Court should disregard these new claims, though they fail on the merits in any event. See Gilmour v. Gates, McDonald & Co., 382 F.3d 1312, 1315 (11th Cir. 2004) ("A plaintiff may not amend her complaint through argument in a brief opposing summary judgment"); Agri-Mark, Inc. v. Niro, Inc., 233 F. Supp. 2d 200, 207 (D. Mass. 2002) ("It is well-settled that plaintiffs are generally not permitted to raise brand new theories of their case in opposition to a motion for summary judgment . . . ."); Marten v. Yellow Freight Sys., Inc., 993 F. Supp. 822, 829 (D. Kan. 1998) ("A claim not raised in the complaint and initially asserted in a response to a summary judgment motion is not properly for the court."). With respect to the first claim, GSK cites Frazier v. Roessel Cine Photo Tech., Inc., 417 F.3d 1230 (Fed. Cir. 2005), for the proposition that "'[a]s a general rule, there is no duty to conduct a prior art search, and thus there is no duty to disclose art of which an applicant could have been aware.'" Id. at 1328 (quoting FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 526 n.6 (Fed. Cir. 1987)). But both Frazier and FMC Corp. were simply describing the state of affairs prior to the Final Rules. There is no indication in either case that the Federal Circuit's statement was prescriptive (*i.e.* suggesting that the USPTO could never require a prior art search through a valid exercise of its § 2(b)(2) authority), rather than descriptive. See 72 Fed. Reg. at 46806 (comment 249). Because GSK's second claim adopts and expands upon Tafas's burden-shifting argument, the USPTO addresses it infra Part I.E.

Only four claims call for additional discussion. *First*, in opposing the USPTO's summary judgment motion, GSK improperly adopts and expands upon Tafas's argument that Final Rules 75 and 265 shift the burden of examination and the burden of establishing a *prima facie* case to the applicant. GSK Opp. at 24; Tafas Opp. at 22. The USPTO has already explained why the requirement of submitting an ESD does not alleviate the USPTO of its duty to examine applications under 35 U.S.C. § 131, nor does it call on applicants to establish a *prima facie* case of patentability. Tafas Opp. at 1-3. The USPTO also explained that although the Court need not reach the issue because the Final Rules do not change who establishes a *prima facie* case, the USPTO could validly require applicants to come forward with a *prima facie* case of patentability in the exercise of its § 2(b)(2) authority. Id. at 3-4.

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[23] Notably, Tafas does not contest that he presently does not have the types of applications that many of his ancillary claims would implicate. See USPTO Mem. at 29 n. 17.

[24] Tafas suggests that the USPTO contradicts itself by using the terms "voluntary divisional" and "involuntary divisional" in the Federal Register but arguing that the term "voluntary divisional" is a misnomer. Tafas Mem. at 26. Tafas neglects to note that when it referenced those terms in the Federal Register, the USPTO always put them in quotation marks and typically preceded them with the word "so-called" to emphasize that while the patent bar might use these terms colloquially, they are not authorized by statute. See, e.g., 72 Fed. Reg. at 46720 (col. 3); 72 Fed. Reg. at 46731 (col. 3).

With respect to the latter issue, GSK now argues that 35 U.S.C. §§ 102 and 103 require the USPTO to establish a *prima facie* case of unpatentability. GSK Opp. at 23-24; compare Tafas Opp. at 24 (resting claim only on purported conflict with "35 U.S.C. §§ 101, 111, 112, 131, and 151"). GSK cites In re Warner, 379 F.2d 1011 (C.C.P.A. 1967), but that case merely confirmed the uncontroversial proposition that §§ 102 and 103 place the ultimate "burden of proof" on the USPTO. Id. at 1016. It did not address the separate question of who should make out a *prima facie* case for the other party to rebut. See In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (describing the origin of Office burden-shifting as "uncertain"). Given that the *prima facie* case is a "procedural tool," In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992), and that Plaintiffs acknowledge the USPTO's authority to promulgate procedural rules, it is hardly consistent for them to contend that the USPTO could not, by rulemaking, alter that burden. Again, however, the Court need not reach this issue because Final Rules 75 and 265 do not, by requiring applicants to provide additional information for examination, relieve examiners of their present burden to establish a *prima facie* case of unpatentability.

Second, Tafas reframes his argument that the Final Rules conflict with objectives of the Bayh-Dole Act, 35 U.S.C. § 200 et seq., now arguing that the USPTO failed to consider the issue. Tafas Opp. at 26. In doing so, he implicitly converts his claim that the Final Rules conflict with the Patent Act into a claim that the USPTO acted arbitrarily or capriciously in failing to consider the issue. See 5 U.S.C. § 706(2)(A). This version of the claim is as untenable as the first, see USPTO Tafas Opp. at 9-10, because the USPTO explicitly addressed the Bayh-Dole Act in its Federal Register notice. 72 Fed. Reg. at 46829 (comment 338).

Third, Tafas accuses the USPTO of mischaracterizing his "argument that Final Rule 1.78(d)(1)(ii) and (iii) improperly prohibits an applicant from filing a continuation-in-part application seeking priority under 35 U.S.C. § 120 through a divisional filed pursuant to 35

U.S.C. § 122 [sic, § 121] without a petition and showing." Tafas Opp. at 25. The USPTO previously understood Tafas to be complaining that the Final Rules were improper because they prevented him from filing a continuation-in-part as a divisional and receiving the protection of § 121. See USPTO Mem. at 31. The USPTO accordingly addressed that argument.[25]

It now appears that Tafas is asserting that Final Rules 78(d)(ii) and (iii) are improper because he believes they prevent him from filing a continuation-in-part as a child of a divisional application and receiving the benefit of the priority date of his initial application under § 120 for that continuation-in-part application. See Tafas Mem. at 25. In fact, the Final Rules do not prohibit filing a continuation-in-part application as a child of a divisional application. Such a continuation-in-part application could be properly filed so long as the requirements of Final Rule 78(d)(1)(i) have been met.[26] The USPTO has already shown, repeatedly, that § 120 does not preclude it from placing reasonable conditions on the filing of continuing applications, see, e.g., supra Part II.B, and divisionals and continuation-in-part applications are simply types of continuing applications. See Archie R. McCrady, PATENT OFFICE PRACTICE 115 (1928) (explaining a divisional is merely one type of continuation application). Thus, there is no reason why the particular sequence of applications Tafas focuses on should not be subject to the petition and showing requirement of Final Rule 78.

Fourth, Tafas contests that the argument that Final Rule 78(f) erodes confidentiality protections of 35 U.S.C. § 122 has been waived because neither he, nor anyone else, raised it to the USPTO.[27] Tafas Opp. at 27-28. Whether or not the USPTO was required to engage in notice and comment rulemaking is irrelevant because, the fact is, it did. Consequently, the public had ample opportunity to inform the USPTO of its objections to the rules, and allowing the USPTO to have to confront new claims for the first time in this litigation would frustrate the purposes of the waiver doctrine and "[t]he notion of deference to agency interpretations of law embodied in Chevron." Ohio v. EPA, 997 F.2d 1520, 1528 (D.C. Cir. 1993); see generally Vt. Yankee Nuclear Power Corp. v. NRDS, 435 U.S. 519, 533-34 (1978). Ohio v. EPA is clearly apposite, as the D.C. Circuit concluded that the plaintiff had waived a "purely legal challenge" that certain regulations were contrary to a statute by failing to bring its objection to the agency's attention during the rulemaking. 997 F.2d at 1528. This Court should conclude the same.

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[25] The USPTO explained that if an applicant filed an application under § 121 but added new matter, it properly would be called a continuation-in-part, not a divisional. USPTO Mem. at 31. Tafas is thus incorrect in writing "§ 121 [sic - § 120]," as the USPTO intended to address § 121. Tafas Mem. at 26.

[26] Of course, the new matter in any continuation-in-part application cannot receive the benefits of §120 because the new matter (*i.e.,* what defines a continuation-**in-part** application) is not supported by the earlier application.

In sum, each of Plaintiffs' claims that the Final Rules violate the Patent Act is meritless and/or not properly before the Court. The Final Rules uniformly comport with the Patent Act.

II. THE FINAL RULES ARE NOT ARBITRARY OR CAPRICIOUS

The USPTO having demonstrated that the Final Rules withstand scrutiny under the deferential standard of Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 43 (1983), see USPTO Mem. at 34-39, Plaintiffs now introduce new arguments, look to extra-record materials, and rely on inapposite case law to suggest that the Final Rules are arbitrary or capricious. GSK Opp. at 42-45. The Court should reject these last-ditch efforts.

A. GSK's "Arbitrary and Capricious" Claims Fail

GSK argues for the first time that the Final Rules are arbitrary or capricious because the USPTO failed to sufficiently weigh the purported costs of the Final Rules against the purported

[27] Besides noting that the argument has been waived, the USPTO has further explained why this claim fails on the merits. See USPTO Mem. at 33; USPTO Tafas Opp. at 5-6.

benefits of GSK's dilatory filing strategy. GSK Opp. at 43. To do so, GSK relies on a case that did not arise under the APA, 5 U.S.C. § 706(2)(A), and thus employed a cost-benefit balancing that has no relevance to this case. GSK Opp. at 43 (citing Ctr. for Biological Diversity v. NHTSA, 508 F.3d 508, 535 (9th Cir. 2007)).[28]

GSK also grossly inflates the so-called "costs" of the Final Rules and does so without reference to any competent evidence. GSK Opp. at 43 (citing, Knowles Decl. ¶¶ 8-19; GSK Opp. 9-12, 35-36; GSK Am. Compl. ¶¶ 57-58, 147-50). As an initial matter, the Final Rules will not "destroy" GSK's inventions, as the Final Rules do not alter the substantive eligibility requirements for patents, and there are numerous avenues for GSK to claim any disclosed but as yet unclaimed inventions. Id.; see USPTO Mem. at 11-13. But even if the Final Rules could be expected to have adverse effects, an extra-record declaration, allegations of a complaint, and arguments of counsel are not competent evidence where "'the focal point for judicial review should be the administrative record already in existence.'" Tafas v. Dudas, — F. Supp. 2d —, 2008 WL 112043, at *3 (E.D. Va. Jan. 9, 2008) ("Tafas II") (quoting Camp v. Pitts, 411 U.S. 138, 142 (1973)). GSK fails to cite a single piece of record evidence of the so-called costs of the Final Rules that the USPTO failed to consider. Moreover, contrary to GSK's contention, the

[28] Specifically, the plaintiff in Center for Biological Diversity challenged new rules promulgated under the Energy Policy and Conservation Act of 1975, 49 U.S.C. §§ 32901-19, which has its own judicial review provision, id. at § 32909, and sets out four specific factors that the Secretary of Transportation must weigh in promulgating regulations, id. at § 32902(f) ("[T]he Secretary of Transportation shall consider technological feasibility, economic practicability, the effect of other motor vehicle standards of the Government on fuel economy, and the need of the United States to conserve energy."). The Ninth Circuit concluded that the NHTSA acted arbitrarily or capriciously because it failed to balance these four factors – factors that do not exist under the APA. Ctr. for Biological Diversity, 508 F.3d at 530, 535. The other case GSK cites, Morall v. DEA, 412 F.3d 165 (D.C. Cir. 2005), is arguably even less relevant, as it did not involve a rulemaking, and the Court found that the DEA's decision to revoke a doctor's certificate of registration showed a "a lapse of reasonable and fair decisionmaking" because the DEA Administrator "entirely ignore[d] the ALJ's credibility findings." Id. at 167.

USPTO explicitly considered the purported benefits of GSK's patenting strategy, among others. 72 Fed. Reg. at 46762 (comment 52).

GSK otherwise disparages the USTPO's budget model through conclusory accusations. GSK Opp. at 44. The USPTO has already explained how its budget model – which was not even created for the purpose of justifying the Final Rules – shows that the Final Rules, along with other initiatives, will enable the pendency of patent applications before first Office actions to level off. USPTO GSK Opp. at 22-24. The USPTO has also explained why its assumptions, based on agency experience and expertise, were reasonable.[29] Id. at 23-24. The USPTO need do nothing more for the Final Rules to stand. See U.S. Air Tour Ass'n v. Fed. Aviation Admin., 298 F.3d 997, 1008 (D.C. Cir. 2002).

B. Tafas's "Arbitrary and Capricious" Claims Fail

Tafas's arbitrary or capricious arguments focus on irrelevant issues raised solely by *amici* and extra-record materials that are not properly before the Court. Despite this Court's admonition "that it may not consider legal issues or arguments that were not also raised by Plaintiffs," Tafas v. Dudas, 511 F. Supp. 2d 652, 660-61 (E.D. Va. 2007) ("Tafas I"), Tafas remarkably "points the Court to the brief of *amici* Polestar Capital and Norseman Group, adopting the arguments therein." Tafas Opp. at 28 (emphasis added). Tafas may not "adopt" the arguments of *amici* that he did not raise in his own summary judgment motion, and the Court should disregard the vast majority of his arbitrary and capricious arguments for this reason alone.

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[29] GSK argues that the budget model either shows that the USPTO will never grant petitions beyond the 2+1 threshold, or that the USPTO fails to account for the efficiency losses that will occur as people file continuations above the 2+1 threshold. GSK Opp. at 44. GSK cannot have it both ways. Since many continued examination filings above the 2+1 threshold are based upon lax practices rather than reasonable diligence, the USPTO reasonably anticipated that many (though not all) such filings would not be able to meet the standard of Final Rule 78(d)(1)(vi). See 72 Fed. Reg. at 46767-77. Accordingly, it accommodated the limited number of filings above the 2+1 threshold that it expects to receive in its model. In any event, the model does not only reflect efficiency gains based on the 2+1 Rule, but also based on the 5/25 Rule. See USPTO GSK Opp. at 24 (explaining reasonable, conservative nature of model estimates).

Tafas's arguments are further inappropriate because they rely on materials that are not in the administrative record and should be stricken. Id. at 29-32 & Exs. 5-13. For example, Tafas claims that a letter sent by Dr. Richard Belzer to the Office of Management Budget ("OMB") dated January 16, 2008 – just two weeks ago – shows that the USPTO did not adequately consider certain paperwork burdens caused by the Final Rules. Id., Ex. 13. But "[t]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court."[30] Camp, 411 U.S. at 142; Tafas II, 2008 WL 112043, at *3. The recent Belzer letter was not before the USPTO during its rulemaking and is not properly before this Court now. In any event, the Belzer letter is directed to OMB's duties to conduct review under the Paperwork Reduction Act, 44 U.S.C. § 3501, et seq. – a regulatory review that, as the USPTO has already explained, is irrelevant to this Court's review of the Final Rules under the APA.[31] See USPTO Tafas Opp. at 15-16.

The Court likewise should not consider the materials that Polestar – and now, by "adoption," Tafas – claim should have been included in the administrative record. Tafas Opp., Exs. 4-12. As the USPTO explained in connection with its Motion to Strike, Plaintiffs had numerous opportunities to argue that the administrative record was incomplete and that the Court

[30] The USPTO made clear that its Motion to Strike represented a standing objection to efforts by the plaintiffs to rely on extra-record material in later briefing. See Defendants' Motion to Strike, Dkt. No. 249, 1 n.1. The Court should now strike the Knowles Declaration, Mem. in Supp. of GlaxoSmithKline's Mot. for Summ. J., Dkt. No. 252, Ex. 4, or at a minimum, disregard it in connection with GSK's APA claims.

[31] The arguments that *amici* Polestar Capital and Norseman Group ("Polestar") raise – and Tafas now attempts to "adopt" – regarding the USPTO's compliance with the Freedom of Information Act, 5 U.S.C. § 552, and the Information Quality Act, 44 U.S.C. § 3516 Note, are similarly irrelevant to this Court's APA review. Tafas Opp. at 30, 32.

should consider materials outside the record in deciding whether the USPTO acted arbitrarily or capriciously. See Mem. in Supp. of Defs. Mot. To Strike ("Strike Mem."), Dkt. No. 250, at 2-3. The Court rejected these arguments. See Tafas II, 2008 WL 112043, at *7 ("Tafas has not made a sufficiently strong or substantial showing of incompleteness to overcome the presumption that the USPTO properly designated the administrative record."). Tafas should not be allowed yet another bite at the administrative record apple, now based solely on the arguments of *amici.*

Regardless, Polestar's arguments do not show that the Final Rules are arbitrary or capricious. The USPTO noted in the brief supporting its Motion to Strike why most of the materials that private parties submitted directly to the OMB in an effort to lobby the OMB to disapprove the Final Rules under Executive Order 12,866 do not belong in the USPTO's administrative record. See Strike Mem. at 6 n.6; Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993). Polestar admits that these documents were submitted to OMB "to assist OMB's review under E.O. 12,866."[32] See Br. of *Amici Curiae* Polestar Capital & Norseman Group in Supp. of Pls. ("Polestar Br."), Dkt. No. 173, at 3. (emphasis added). Tafas objects that these documents are "relevant" to the Final Rules, Tafas Opp. at 30, but that is not the test for what belongs in an administrative record. Rather, an administrative record must contain "all documents and materials directly or indirectly considered by the agency." Bar MK Ranches v. Yuetter, 994 F.2d 735, 739 (10th Cir. 1993). Here, the pertinent "agency" is the USPTO, not the OMB. While the USPTO included in the administrative record any of the OMB materials that it directly or indirectly considered, the USPTO appropriately did not include those it did not.[33]

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[32] The documents referenced in Polestar's brief and summarized by Tafas in a table all date from May 2007 to July 2007, when the USPTO had completed the Final Rules and they were in the hands of OMB for final review pursuant to the Executive Order. See Office of Information and Regulatory Affairs (OIRA), Executive Order Reviews Completed between January 1, 2007 to December 31, 2007, at p. 5, available at http://www.reginfo.gov/public/do/eoHistReviewSearch (Department of Commerce, 2007) (showing that OMB received the Final Rules on April 10, 2007 and completed its review on July 9, 2007); Tafas Opp. at 29, Tbl. 1.

In any event, it could not have been "prejudicial error" for the USPTO not to include in its record documents that private parties submitted to OMB. 5 U.S.C. § 706 ("In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error."). Tafas fails to show that these OMB documents introduce arguments that the USPTO had not already considered in reviewing the public comments that were submitted during the notice and comment period. Accordingly, he has not demonstrated that the USPTO "entirely failed to consider an important aspect of the problem" or made a "clear error of judgment" under State Farm, 463 U.S. at 43.

In his final "arbitrary or capricious" argument, Tafas at last focuses on materials that are in the administrative record; however, he compares apples, oranges, and bananas to suggest that there are inconsistencies in the USPTO's data where none exist. Tafas Opp. at 32. The first statistic he cites shows that 82.1% of all applications pending as of July 2006 had ten or more total (*i.e.,* independent and dependent) claims. A04552. By contrast, the second statistic shows that 1.2% of nonprovisional applications filed between January 1, 2005 and October 13, 2005 contained more than ten independent claims. Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61, 62 (Jan. 3, 2006). Unlike the first two statistics, the third statistic – which references 2.7% of applications – has nothing to do with claims, or the representative claims approach of the Proposed Rules. 72 Fed. Reg. at 46754-55. It instead refers to the number of applications that would be affected by Final Rules 78 and 114, which related to continuations and RCEs. It is not surprising – much less arbitrary or capricious – that measuring three different universes would yield three different statistics.[34]

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[33] Underscoring the USPTO's careful efforts in compiling its administrative record, the agency concluded that two of the OMB documents belonged in the record that it certified on October 5, 2007. See Tafas Opp. at 29, Tbl. 1(citing A08503-04; A08433-42, A08506-15). It included the first, a May 16, 2007 meeting record, because Under Secretary Dudas – the agency's final decision-maker – personally attended that one OMB meeting to represent the USPTO. A08503-04. The USPTO included the second document, a letter from David E. Boundy to the Administrator of OMB because, as the cover e-mail shows, it was specifically forwarded from OMB to the USPTO, not only submitted to the OMB. See A08433-42, A08506-15. It is wholly inappropriate for Tafas to suggest that the USPTO omitted any OMB materials because they contain "information unfavorable to the USPTO," when the administrative record is replete with unfavorable comments, including the Boundy letter. Tafas Opp. at 30.

In the end, the USPTO's 127-page Federal Register notice and voluminous administrative record amply support the Final Rules and satisfy the agency's obligations under State Farm.

III. THE FINAL RULES ARE NOT RETROACTIVE IN THEIR CURRENT APPLICATION

Plaintiffs persist in arguing that the applicability of the Final Rules to certain pending applications render them retroactive under Landgraf v. USI Film Products, 511 U.S. 244 (1994), but even in their current application, the rules neither impair rights that applicants currently possess, nor impose new duties on completed transactions.[35] As the Court made clear in Landgraf, a regulation "does not operate retrospectively merely because it is applied in a case arising from conduct antedating the [regulation's] enactment or upsets expectations based in prior law."[36] 511 U.S. at 269.

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[34] At the end of his brief, Tafas argues for the first time that "the USPTO's assertions of continuation abuse is [sic] not supported by the evidence." Tafas Opp. at 41. Tafas does not explain what claim he believes this discussion supports, but it should most likely be construed as a meritless "arbitrary or capricious" claim. The USPTO described in the Federal Register the types of applicant practices that it considers to be abusive and how these practices impair the efficiency and quality of patent application examination. See 72 Fed. Reg. at 46719. As Tafas notes, "*all amici* supporting USPTO's position in this case join the allegations that the continuation practice is being abused," thus underscoring that the USPTO is not alone in perceiving these practices to be harmful and vexatious. Tafas Opp. at 41-42. That Tafas disagrees with these characterizations does not render the Final Rules arbitrary or capricious.

[35] The applicability of each of the Final Rules is set out in the Federal Register notice and is not intrinsic to the Final Rules themselves. See 72 Fed. Reg. at 46716, 46736 (making Final Rules 78(d) and 114(g) applicable to initial and continuing applications filed after November 1, 2007); id. at 46716, 46728 (making Final Rules 75 and 265 applicable to applications filed on or after November 1, 2007 and pending applications for which a first Office action on the merits had not been mailed as of that date).

A. The Procedural Nature of the Rules Is Relevant, Even if Not Dispositive

GSK takes issue with the Supreme Court's statement that "[c]hanges in procedural rules may often be applied in suits arising before their enactment without raising concerns about retroactivity." Landgraf, 511 U.S. at 275. The USPTO has never argued that because the Final Rules are procedural, the retroactivity inquiry is at an end. Instead, the USPTO noted that "[a]s a threshold matter, the Final Rules do not seriously implicate retroactivity concerns" because they are procedural. USPTO Mem. at 39. This is a correct statement of the law, and an appropriate factor for the Court to consider. Rep. of Austria v. Altmann, 541 U.S. 677, 697 (2004) ("Under Landgraf, therefore, it is appropriate to ask whether the Act affects substantive rights (and thus would be impermissibly retroactive if applied to preenactment conduct) or addresses only matters of procedure (and thus may be applied to all pending cases regardless of when the underlying conduct occurred.")); see Combs v. Comm'r of Soc. Sec., 459 F.3d 640, 647 (6th Cir. 2002) (en banc) ("The Supreme Court in Landgraf and Altmann, and our court in Patel, have recognized that changes to procedural rules generally do not have retroactive effect because procedural rules regulate secondary as opposed to primary conduct.").

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[36] GSK simplistically asserts that because the Office expects the Final Rules to help reduce the backlog, they must be retroactive. GSK Opp. at 28. The Final Rules will reduce the backlog by improving the efficiency of future patent application examination so that examiners will finally have time to examine the applications now pending in the backlog. See 72 Fed. Reg. at 46719 (explaining that Final Rules 78 and 114 "will permit the Office to apply the patent examining resources otherwise consumed by [continuation] applications to the examination of new applications and thereby reduce the backlog of unexamined applications"). By placing reasonable conditions on the filing of future continuing applications, Final Rules 78 and 114 will cause applicants to prosecute their applications with greater diligence and focus, thereby streamlining their submissions to the agency. Id. at 46720. Final Rules 75 and 265 will expedite examination by requiring applicants who submit large numbers of claims for examination to provide the Office information about those claims. Id. at 46720-21. These forward-looking efficiency gains do not remotely render the Final Rules retroactive.

B. The Final Rules Do Not Impair Applicants' Rights

Plaintiffs persist in asserting that there is a "*quid pro quo*" or "bargained-for exchange of trade secret rights for the protections afforded by existing patent laws," even though the USPTO has shown this theory to be a fallacy. GSK Opp. at 30; Tafas Opp. at 35. Plaintiffs still cite no authority for the proposition that any such exchange exists. Indeed, even *Amicus* American Intellectual Property Lawyers Association ("AIPLA") admits that "[t]he filing of an initial application does not immediately cause the loss of the trade secrets disclosed in the application." Br. for *Amicus Curiae* Am. Intellectual Prop. Law Ass'n ("AIPLA"), Dkt. No. 185, at 2. As the USPTO explained in its opening brief, applicants themselves extinguish any trade secrets they may have had when they fail to ask the USPTO to retain their applications in confidence – something the USPTO would do if the applicant so elected.[37] See 35 U.S.C. § 122(b)(2)(B)(i); USPTO Mem. at 43 (citing Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002 (1984)).

In responding to the USPTO, GSK exposes what is behind the facade of its "*quid pro quo*" argument: an attempt to claim rights in a particular regulatory regime. GSK contends that it "sacrificed its trade secrets in exchange for the full spectrum of protection afforded under the

[37] GSK contends that the USPTO's argument is an improper "*post hoc* rationalization" of counsel, but GSK misapplies the principle it attempts to assert. GSK Opp. at 32 n. 27. The maxim that an agency may not rely on *post hoc* rationalizations means that a court will look to the administrative record, not to bases for an agency action first raised in litigation, in deciding whether an agency action withstands review under the APA, 5 U.S.C. § 706(2)(A). See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 419 (1971) (citing Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168-69 (1962)); In re Sang Su Lee, 277 F.3d 1338, 1345-46 (Fed. Cir. 2002). The question of whether the Final Rules are retroactive is a legal question distinct from whether the USPTO acted in an arbitrary or capricious manner under the APA. It is entirely appropriate for USPTO counsel to raise new legal arguments in response to that question. Moreover, it is unclear how GSK could expect the USPTO to have previously responded to an argument that it raises for the first time in litigation. The USPTO addressed the retroactivity issues that were raised to it in the Federal Register, 72 Fed. Reg. at 46826-27, but could not have addressed the notion of a *quid pro quo*, which was not brought to its attention in the context of retroactivity.

current system, including the ability to seek patent protection abroad." GSK Opp. at 33 (emphasis added). In other words, GSK believes it has a right to have the "current system," in which it files limitless continuing applications, persist. Id. To the contrary, procedures do not give rise to cognizable rights, Olim v. Wakinekona, 461 U.S. 238, 250 (1983); Fleury v. Clayton, 847 F.2d 1229, 1231 (7th Cir. 1988), and GSK cannot claim rights in the continued operation of particular regulatory regimes, Prometheus Radio Project v. F.C.C., 373 F.3d 372, 430 (3d Cir. 2004). Nor does the Patent Act itself afford GSK any "right" to delay filing continuing applications or to refuse to provide information to the Office. See supra Parts I.B-D.

Because GSK's "*quid pro quo*" argument is a fallacy, Plaintiffs are unable to distinguish the USPTO's cases, which show that pending applications do not give rise to rights that can be impaired by new rules. See GSK Opp. at 30-31 & n.24 (attempting to distinguish Bellsouth Telecomms., Inc. v. Southeast Telephone, Inc., 462 F.3d 650, 660-61 (6th Cir. 2006); Pine Tree Med. Assocs. v. Sec. of Health & Human Servs., 127 F.3d 118, 121 (1st Cir. 1997); Chadmoore Commc'n v. FCC, 113 F.3d 235, 240-41 (D.C. Cir. 1997); Bergerco Canada v. U.S. Treas. Dep't, 129 F.3d 189, 195 (D.C. Cir. 1997), on the grounds that they lack a "tradeoff"). For the same reason, INS v. St. Cyr, 533 U.S. 289 (2001), which involved a true plea bargain and concerns constitutional rights in a criminal context, is inapt.

Finally, GSK continues to err in arguing that patent applications give rise to property rights. The Supreme Court has held to the contrary. See Marsh v. Nichols, Shepherd & Co., 128 U.S. 605, 612 (1888). GSK cannot seriously contend that Ruckelshaus stands for the proposition that "patent applications are constitutionally protected property," GSK Opp. at 32, when Ruckelshaus concerned trade secrets disclosed by applications for registration under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq., and had nothing to do with patent applications. See also infra Part IV.B.1 (further explaining why patent applications are not property under Ruckelshaus).

GSK also overstates the importance of 35 U.S.C. §§ 154(d) and 261. GSK Opp. at 31; see also Tafas Opp. at 34. The USPTO has already explained why § 261 in fact shows that patent applications – as distinguished from patents – are not property, and why the enactment of § 261 in 1952 thus did not upset Supreme Court and other precedent holding that patent applications are not property. See USPTO GSK Opp. at 33-34 & n. 30. The language of § 154(d), entitled "Provisional Rights," similarly underscores that any rights lie in a patent, not a patent application, for the provisional rights of this section accrue only upon the grant of a patent. See 35 U.S.C. § 154(d)(1) ("[A] patent shall include the right to obtain a reasonable royalty from any person" who used the invention claimed in a published patent application between when it was published and when a patent issued); id. § 154(d)(2) (providing that the rights under (d)(1) are available only where the invention claimed in the patent application is substantially identical to the invention in the published patent); see Philippe Signore, The New Provisional Rights Provision, 82 J. Pat. & Trademark Off. Soc'y, 742, 745 (2000) ("[P]rovisional rights remedies cannot be triggered until a patent actually issues. In other words, the new rights exist in a patent, not in a patent application. If the patent never issues, then no rights exist, thus the name 'provisional' rights."). For all of these reasons, GSK fails to identify any cognizable right that the Final Rules could impair.[38]

C. The Final Rules Do Not Impose New Duties on Completed Transactions

GSK misunderstands the USPTO to be arguing only that patent applications are not

[38] GSK criticizes the USPTO's use of the term "vested rights" in its opening brief, even though the term is used repeatedly in Landgraf itself. See Landgraf, 511 U.S. at 269. In stating that the Court does "not restrict the presumption against retroactivity to cases involving vested rights," id. at 275 n. 29, Landgraf simply recognizes that there are other ways that laws may be retroactive, e.g., by imposing new duties on completed transactions. In any event, GSK has pointed to no "rights" of any kind that the Final Rules impair.

completed transactions. GSK Opp. at 33. Although the USPTO does make that argument, and supports it with compelling case law, USPTO Mem. at 43-44, the USPTO also contends that while the Final Rules create some new procedural devices, they ultimately aim to enforce existing duties across-the-board, USPTO GSK Opp. at 26-27. For example, as to Final Rules 78 and 114, an applicant is already prohibited from presenting papers to the Office "to cause unnecessary delay or needless increase in the cost of prosecution before the Office." 37 C.F.R. § 10.18(b)(2)(i) (2006). And, as to Final Rules 75 and 265, at least one commentator has argued that it is a violation of existing USPTO rules forbidding practitioners to handle legal matters without adequate preparation to file an application without conducting a prior art search. See 72 Fed. Reg. at 46806 (citing Thomas Schneck, The Duty to Search, 87 J. Pat. & Trademark Off. Soc'y 689, 696-701 (2006)). Although the USPTO has not previously adopted this commentator's view, it would be in its discretion to do so in interpreting its own rules. See 37 C.F.R. § 10.77(b) (2006) (precluding a practitioner from handling a legal matter without adequate preparation under the circumstances). The USPTO has further shown that the Final Rules do not "attach new legal consequences to events completed before its enactment," the central inquiry underlying Landgraf's second prong. Landgraf, 511 U.S. at 269-70. USPTO GSK Opp. at 28; USPTO Mem. at 43-44.

In short, Plaintiffs fails to show that the procedural Final Rules run afoul of either Landgraf prong, or the considerations of fair notice, reasonable reliance, and settled expectations that animate them. Accordingly, the Court should uphold the Final Rules in their current application.[39]

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[39] In the event the Court were to conclude that any of the Final Rules are retroactive in their current application, the appropriate remedy would be to allow the offending rule to go into effect with respect to future-filed applications. GSK disputes this proposition, but cites only an asylum case that concerned neither a rulemaking, nor the issue of retroactivity. GSK Opp. at 32

IV. GSK's "Administrative-Law Based Takings Claim" Fails

A. The USPTO Adequately Addressed Takings Issues

The USPTO has already shown that its Federal Register notice adequately addressed the host of questions underlying the takings issue, which is enough to foreclose GSK's self-described "administrative-law based takings claim."[40] GSK Opp. at 36; see USPTO GSK Opp. 31-33 (citing 72 Fed. Reg. at 46826-28, 46834); cf. State Farm, 463 U.S. at 43 (holding that a rule is arbitrary or capricious only if the agency "entirely" fails to address a relevant issue); Nat'l Wildlife Found. v. ICC, 850 F.2d 694, 705 (D.C. Cir. 1988) (remanding takings issue where the ICC failed to address the takings question).

The Court could not expect the USPTO to have engaged in a more expansive takings discussion. GSK argues that "[a]ny new continuing application involves a separate piece of property, 100 percent of which will be taken if the PTO denies the filing." GSK Opp. at 37 (emphasis added). In doing so, GSK admits that its takings claim depends on two contingencies: if a "new continuing application" is filed in the future, and "if the PTO denies the filing." Id. But Supreme Court case law "'uniformly reflect[s] an insistence on knowing the nature and extent" of the property right at issue "before adjudicating the constitutionality of the regulations that purport to limit it.'" Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1011 (1992) (quoting MacDonald, Sommer & Frates v. Yolo County, 477 U.S. 340, 351, 106 (1986)). Thus,

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n. 26 (citing INS v. Orlando Ventura, 537 U.S. 12 (2002)). The Supreme Court has made clear that where a statute is retroactive, the court should construe it as "inapplicable to the event or act in question." Fernandez-Vargas v. Gonazles, 126 S. Ct. 2422, 2428 (2006). There is nothing about a regulation that requires a different result. It is unnecessary to remand for the USPTO to re-promulgate the identical rules but publish new applicability dates in the Federal Register.

[40] As noted in an earlier brief, Tafas has waived any takings claim by failing to raise it in his amended complaint. USPTO GSK Opp. at 31 n. 27. Whether or not Tafas tried to raise a claim under the Takings Clause in his withdrawn preliminary injunction motion, when his amended complaint cites only the Due Process Clause, is plainly irrelevant. U.S. Const. Am. V; Tafas Opp. at 35. Regardless, Tafas says nothing that would show the existence of a taking. Id.

in Williamson County Regional Planning Commission v. Hamilton Bank of Johnson City, 473 U.S. 172 (1985), the Court held that the takings claim was unripe, as the Court could not evaluate whether a taking had occurred "until the administrative agency has arrived at a final, definitive position regarding how it will apply the regulations at issue to the particular land in question." Id. at 190 (emphasis added).

GSK chastises the USPTO for not saying more about the takings issue, but like the Supreme Court in Williamson County, the agency could not have done so absent a more particularized application of the Final Rules to a concrete, existing piece of property. A remand for the USPTO to say more about an unripe and abstract takings issue would be futile and unwarranted, particularly where the issue raises a purely legal question that this Court could resolve in the first instance to the extent it is not too abstract for resolution.

B. Any Purported Inadequacy In the USPTO's Explanation Could Not Have Been "Prejudicial Error" Absent Valid Takings Concerns

Even if the Court believes the USPTO should have said more, the Office could not have committed "prejudicial error" because the Final Rules could not effect a taking. 5 U.S.C. § 706.

1. Patent Applications Are Not Property Under the Fifth Amendment

As an initial matter, there is no Fifth Amendment property right at issue. GSK stakes its claim to a property right on the notion that patent applications are property, GSK Opp. at 35, but it still has provided no controlling authority for that proposition and fails to rebut Marsh v. Nichols, Shepherd & Co., 128 U.S. at 612. The USPTO addressed in the context of retroactivity why Ruckelshaus, a FIFRA case, does not speak to whether patent applications are property. See supra Part III.B.[41] GSK focuses on the portion of Ruckelshaus where the Court identified certain

[41] The USPTO also addressed, supra Part III.B, why 35 U.S.C. §§ 154(d) and 261 merely underscore that patent applications are not property. See also USPTO GSK Opp. at 34 & n. 30.

characteristics of trade secrets that make them similar to tangible property, 467 U.S. at 1002-04, and argues that because there are a handful of non-binding cases identifying similar characteristics in patent applications, they must be property too. GSK Opp. at 35-36.

GSK overlooks that before discussing these characteristics, the Ruckelshaus Court first stated that "because of the intangible nature of a trade secret, the extent of the property right therein is defined by the extent to which the owner of the secret protects his interest from disclosure to others." 467 U.S. at 1002 (emphasis added). In other words, the Court explained, the defining feature that makes a trade secret property is the power to exclude others from its possession by keeping it a secret. In Marsh, the Supreme Court explained that a patent application lacks this defining feature, which is only acquired when a patent is granted:

> The invention is the product of the inventor's brain, and if made known would be subject to the use of any one, if that use were not secured to him. Such security is afforded by the act of congress when his priority of invention is established before the officers of the patent-office, and the patent is issued. The patent is the evidence of his exclusive right to the use of the invention; it therefore may be said to create a property interest in that invention. **Until the patent is issued, there is no property right in it; that is, no such right as the inventor can enforce**. Until then there is no power over its use, which is one of the elements of a right of property in anything capable of ownership.

Marsh, 128 U.S. at 611-12 (emphases added). The Supreme Court has established, therefore, that patent applications lack the "defin[ing]" feature of intangible property under Ruckelshaus and are not property.

Although GSK points to the Manbeck Declaration to support its argument that patent applications are property, Manbeck never actually draws that conclusion. See GSK Opp. at 35 (citing Manbeck Decl. ¶ 21 (stating only that patent applications have "indicia of constitutionally protected property")). This is not surprising, given that Manbeck reached the exact opposite conclusion when he was Commissioner of Patents. In In re Patecell, 19 U.S.P.Q. 2d 1390 (Comm'r of Pat. & Trademarks 1991) (Ex. 2, slip op. at 9-10), Commissioner Manbeck rejected a Fifth Amendment due process claim, stating, "Petitioner has not shown, as of November 5, 1990, that his allowed patent application, but unissued patent, was property within the meaning of the Fifth Amendment on November 5, 1990." Id. at 1393 (citing Brenner v. Ebbert, 398 F.2d 762, 764 (D.C. Cir.), cert. denied, 393 U.S. 926 (1968); DeFerranti v. Lyndmark, 30 App. D.C. 417, 426 (1908)).[42] Then-Commissioner Manbeck was correct.

2. *No Taking Would Occur Under Lucas or Penn Central*

Nor could the Final Rules effect a taking of property even if patent applications were property. GSK relies on Lucas v. South Carolina Coastal Council, 505 U.S. 1003 (1992), but admits that Lucas applies only where there is a "*per se* . . . regulatory taking that destroys 100 percent of a particular element or parcel of property." GSK Opp. at 37. GSK argues that "[a]ny new continuing application involves a separate piece of property, 100 percent of which will be taken if the PTO denies the filing." Id. GSK's asserted taking necessarily rests on the premise that an applicant already has two pending continuing applications in an application family and has exhausted his "one more" continuation filing by the time the Final Rules take effect. 72 Fed. Reg. at 46733 (explaining "one more"). Otherwise, the applicant would not even need to consider filing a petition in order to pursue protection for its unclaimed inventions.

But even assuming that singular scenario, the applicant still would not need to file a petition. The applicant could, instead, simply amend the claims in one of its pending applications to add any disclosed but as-yet unclaimed inventions. MPEP § 714(i) (Rev. 6, Sept. 2007). The applicant could accompany that amendment with a suggested restriction requirement ("SRR"), and, once the SRR is accepted, file a divisional application for the new inventions.[43] 72

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[42] The USPTO, of course, relies on the same cases in its briefs. See USPTO Mem. at 41.

[43] Because an application itself is valueless except to the extent it may someday yield a patent on an invention and thereby provide exclusionary rights, see Marsh, 128 U.S. at 611-12,

Fed. Reg. at 46842; 37 C.F.R. § 1.142. GSK has never explained why this straight-forward option would not enable it to claim each of its multiple inventions. The Court cannot be satisfied with the bald assertion that such options are "insurmountable" when a constitutional question is on the line.[44] GSK Opp. at 34 n. 28.

GSK and Tafas also suggest that the USPTO has not adequately considered the three-factor test of Penn Central Transp. Co. v. City of New York, 438 U.S. 104 (1978) – the only test that is relevant – but it is Plaintiffs who have not come to terms with Penn Central, or the broader principles that animate the takings inquiry. GSK Opp. at 38; Tafas Opp. at 35. Plaintiffs fail to address any of the Supreme Court case law explaining that regulatory changes that affect the public generally are not takings, and that where an owner possesses a bundle of property rights, the destruction of a single strand does not constitute a taking. See USPTO Mem. at 46-47.

As for the Penn Central factors, Plaintiffs' briefs fail to engage with the critical first factor – the character of the governmental action – which weighs strongly against them. Penn Central, 438 U.S. at 124 (explaining that a taking more readily occurs when there is a "physical invasion" by the government). Second, while Plaintiffs would like the Court to ignore the steps the USPTO has taken to allow applicants to claim all of their disclosed but unclaimed inventions, and thereby mitigate any economic impact of the rules, controlling authority requires the Court to consider them. See Connolly v. Pens. Benefit Guar'y Corp., 475 U.S. 211, 226-26 (1986)

GSK distracts this Court by focusing on whether an "application" is being taken. Unless the underlying invention could not be claimed, nothing of value could be taken.

[44] This is particularly true when GSK has failed to specifically controvert the statement in the USPTO's Statement of Material Undisputed Facts that "Final Rule 142 helps ensure that an applicant who has multiple inventions will be able to claim each of those inventions under the Final Rules." USPTO Mem. at 12; see Local Civ. R. 56(B) ("[T]he Court may assume that facts identified by the moving party in its listing of material facts are admitted, unless such a fact is controverted in the statement of genuine issues filed in opposition to the motion.").

(considering the "significant number of provisions in the Act that moderate and mitigate the economic impact"); Cienega Gardens v. United States, 503 F.3d 1266, 1279 (Fed. Cir. 2007) (criticizing lower court for failing to consider benefits "which were specifically designed to ameliorate the impact" of the new rules). These steps, which mitigate not only the second Penn Central factor (economic impact), but also the third factor (the effect on reasonable investment-backed expectations), include: (i) the ability of applicants to file as many continuing applications as they desire before the Final Rules take effect; (ii) the ability to file "one more" application after the Final Rules become effective, 72 Fed. Reg. at 46733; (iii) the ability to amend claims in pending applications, MPEP § 714(i), and file an SRR under Final Rule 142 to start divisional families after the Final Rules become effective; and (iv) the right to seek a waiver of the Final Rules by petitioning under 37 C.F.R. § 1.183 (2006) and then seeking judicial review in an APA action if the petition is denied. See generally USPTO Mem. at 12-13. Under these circumstances, a taking under Penn Central could not exist.

Accordingly, although the USPTO adequately considered the takings issues in the Federal Register notice, any failure to do so could not have been "prejudicial error." 5 U.S.C. § 706.

V. TAFAS'S PATENT CLAUSE CLAIMS FAILS

Tafas makes clear in his opposition brief that he seeks to raise two different claims under the Patent Clause, U.S. Const. art. I, § 8, cl. 8, one implicating "separation of powers," and the other concerning whether the USPTO adequately considered the preambular language of that Clause. Tafas Opp. at 35-36. Both claims are meritless.

What Tafas now calls his "separation of powers" claim fails for reasons the USPTO has already addressed, including that it was not pled in Tafas's amended complaint. See USPTO Tafas Opp. at 20-21; Tafas Am. Compl. ¶ 60. In addition, it is now evident that Tafas misapprehends a central tenet of the separation of powers doctrine. While the notion of separation of powers means that the three branches of Government must not have control over each other, "our constitutional system imposes upon the Branches a degree of overlapping responsibility, a duty of interdependence as well as independence the absence of which 'would preclude the establishment of a Nation capable of governing itself effectively.'" United States v. Mistretta, 488 U.S. 361, 381 (1989) (quoting Buckley v. Valeo, 424 U.S. 1, 121 (1976)). Congress's delegation of rulemaking authority to the USPTO through 35 U.S.C. § 2(b)(2) is a prime example of the Branches working interdependently, with "overlapping responsibility," to ensure a patent system that works effectively. Id. Far from violating separation of powers principles, therefore, the USPTO's exercise of its § 2(b)(2) authority to enact the Final Rules effectuates our constitutional system's design for good government.

The USPTO addressed Tafas's second claim, which arises from the Patent Clause's preamble, in its opening and opposition briefs, and Tafas fails to point to any authority beyond what the USPTO previously discredited. See USPTO Tafas Opp. at 21-23; USPTO Mem. at 50-52. Instead, Tafas simply "stands on his position that the ridding itself of a self-induced backlog is not rationally related to whether the rules promote the progress of science and the useful art." Tafas Opp. at 36. Although Tafas finally admits that the USPTO need only withstand rational basis review, Tafas II, 2008 WL 112043, at *12, he fails to appreciate two critical facts. First, the backlog is not "self-induced," but rather is caused by a variety of factors, including the repetitive and vexatious filing of continuation applications and the submission of burdensome numbers of claims for examination. See 72 Fed. Reg. at 46719, 46721. Second, reducing the backlog is only one rationale for the Final Rules, and even that goal promotes the progress of science and the useful arts by enabling the USPTO to examine applications for new innovations rather than continuing to recycle endless continuations and wade through large numbers of claims without assistance. Id. at 46719. While Tafas may dislike the Final Rules, he cannot show that they lack a rational basis.

VI. PLAINTIFFS' VAGUENESS CHALLENGE FAILS AS A MATTER OF LAW

GSK now asserts that the Court should enjoin Final Rule 265 under the broad "fair notice" doctrine because the rule does not put applicants on notice of how to comply with the preexamination search requirement.[45] GSK's refashioned Due Process claim fails for the lack of a property right. In any event, the Final Rules are sufficiently clear to satisfy Due Process.

A. Plaintiff's Vagueness Challenge to Rule 265 Fails Even Under the Fair Notice Doctrine

Tacitly acknowledging that Nyeholt v. Secretary of Veterans Affairs, 298 F.3d 1350, 1356 (Fed. Cir. 2002), forecloses its void-for-vagueness challenge because Final Rule 265 relates to obtaining a government benefit rather than prohibiting conduct or regulating First Amendment rights, GSK now attempts to widen its challenge by asserting that Final Rule 265 must be stricken under the broader "fair notice" doctrine.[46] See GSK Opp. at 24-26. As the Supreme

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[45] Tafas does not set out a clear theory of vagueness or address the USPTO's arguments, but rather asserts, summarily, that the purported vagueness of Final Rule 265 suggests that the rule is arbitrary or capricious. Tafas Opp. at 36-37. This argument, which he raises for the first time in his opposition brief, lacks merit for the reasons set forth herein and in the USPTO's opposition memorandum. See USPTO GSK Opp. at 37-42.

[46] In a footnote, GSK summarily dismisses the Federal Circuit's binding decision in Nyeholt on the grounds that the "facts of Nyeholt bear no relation to this case," but the case is clearly apposite. GSK Opp. at 26 n. 19. In Nyeholt, the plaintiff – who had been assigned a disability rating of 100% in connection with a service-related injury – asserted that the challenged regulation was unconstitutionally vague because it did not provide him with sufficient notice of what evidence he was required to present in order to maintain his disability rating, and thus his benefits. 298 F.3d at 1351. The Federal Circuit concluded that because the plaintiff was merely seeking a benefit from the government, he failed to raise a constitutional challenge that was cognizable under the void-for-vagueness doctrine. Id. at 1357. Other than baldly asserting that the facts in Nyeholt are different than those presented here, GSK fails to articulate how the facts of that case render its holding inapposite. Nyeholt makes clear that the void-for-vagueness doctrine is limited to statutes and regulations that prohibit conduct or regulate First Amendment rights. Id. Because Final Rule 265 simply regulates the manner in which plaintiffs obtain a government benefit, Plaintiffs cannot show that the rule may be found void-for-vagueness.

Court explained in United States v. Lanier, 520 U.S. 259, 266 (1997), there are three manifestations of the "fair warning" or "fair notice" doctrine, of which the void-for-vagueness doctrine is one. Id. GSK previously rested its challenge solely on Lanier's discussion of the void-for-vagueness doctrine. See Mem. in Supp. of GlaxoSmithKline's Mot. for Summ. J., Dkt. No. 142, at 28 (citing Lanier, 520 U.S. at 266, for the proposition that a regulation is vague when it "either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application"). Explaining that "Due Process . . . is not so narrow," GSK now seeks to broaden its claim to the "fair notice" doctrine writ large. GSK Opp. at 25.

Although the fair notice doctrine is broader in scope than the void-for-vagueness doctrine, it is nevertheless inapplicable here. As GSK's own cases demonstrate, the "fair notice" doctrine is rooted in "traditional concepts of Due Process," and thus depends on the existence of some cognizable property or liberty interest. Id.; see, e.g., Gen. Elec. Co. v. EPA, 53 F.3d 1324, 1328 (D.C. Cir. 1995) ("[D]ue process requires that parties receive fair notice before being deprived of property."); United States v. Chrysler, 158 F.3d 1350, 1354-55 (D.C. Cir. 1998) (recognizing a due process right where the regulated entity risked losing property). To establish a property interest, GSK again points to its patent applications. See GSK Opp. at 26 ("Here, there is a palpable risk to GSK and others of a 'penalty': failure to comply with Final Rule 265's incomprehensible requirements will result in abandonment of the application, *i.e.,* loss of property rights."). But as explained earlier, GSK has no property rights in those applications. See supra Part IV.B.1. Lacking any cognizable property rights, GSK's invocation of the "fair notice" doctrine fails to breathe life into the claim that Nyeholt first defeated.

B. Final Rule 265 is Constitutionally Clear

Even if GSK could proceed under the "fair notice" doctrine, however, applicants have fair notice of what Final Rule 265 requires. The substantive analysis for "fair notice" and "void-for-vagueness" is largely the same. See United States v. Kay, — F.3d — , 2007 WL 3088140, *19 n.16 (5th Cir. Oct. 24, 2007) ("Void for vagueness analysis is, however, therefore still applicable to the question of vagueness in a fair notice case."). As GSK concedes, see GSK Opp. at 27, the Constitution does not require agencies to draft regulations with "mathematical certainty" or "meticulous specificity," Grayned v. City of Rockford, 408 U.S. 104, 110 (1972). Indeed, "[i]f by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expects parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation." Gen. Elec. Co., 53 F.3d at 1329; see also United States v. S. Ind. Gas & Elec. Co., 245 F. Supp. 2d 994, 1011-12 (S.D. Ind. 2003) (considering the following factors to determine whether a regulation provides sufficient notice: (i) language of the regulation, (ii) other public statements of the agency, (iii) the consistency of those public statements, (iv) the agency's pre-enforcement efforts to bring about compliance, (v) confusion within the agency as to the proper interpretation of a regulation, and (vi) whether a confused defendant makes inquiry about the meaning of a regulation). Final Rule 265 meets that standard for the reasons the USPTO has already set out. See USPTO Mem. at 54-58.

GSK complains that in light of the Rules' vagueness, "there is a palpable risk to GSK and others of a 'penalty' . . . abandonment of the application, *i.e.*, loss of property rights." GSK Opp. at 26. But even assuming that GSK would lose property rights (which it will not), its applications will not be subject to any risk of immediate loss or forfeiture in light of Final Rule 265's cure provision. See 72 Fed. Reg. at 46843; 37 C.F.R. § 1.265(e). Instead, applicants like GSK will be notified of how their search is non-compliant and given an opportunity to correct any deficiencies. See 35 U.S.C. § 132(a) (providing that when a requirement is imposed on an applicant, the Office must "stat[e] the reasons for such . . . requirement, together with such information and references as may be useful"). Although GSK may see this cure as "bitter medicine," GSK Opp. at 27, its availability undermines GSK's challenge.

GSK next complains that the USPTO cannot rely on subsequently issued guidance or the Manual of Patent Examination Procedure ("MPEP") because neither was issued pursuant to notice and comment rulemaking. GSK Opp. at 27. GSK further argues that, in any event, the guidance therein does not sufficiently clarify the vague aspects of Rule 265. The USPTO fully addressed those arguments in its opening and opposition memoranda, and in the interest of economy, will not repeat them here. See USPTO Mem. at 55-56; USPTO GSK Opp. at 40-42.

Finally, GSK argues that the USPTO's "own" Patent Public Advisory Committee ("PPAC") opined that the preexamination search requirement was vague. GSK Opp. at 28 (citing Ex. 25 at A01295). The PPAC serves the Office in an advisory capacity, and the Office is free to accept or reject its advice. Thus, any statements by the PPAC about the preexamination search were merely advisory, and do not reflect an official USPTO position that could be viewed as inconsistent with other agency statements. Finally, it should be noted that the PPAC submitted its comments and criticisms regarding the preexamination search on May 3, 2006, well before the Office issued any of its subsequent guidance clarifying the Rule. The PPAC's comments on the Proposed Rule, in the absence of the guidance, are irrelevant to the issue now before the Court. Indeed, by issuing such extensive guidance, the USPTO can be regarded as having followed the PPAC's advice to clarify the requirements.

VII. THE FINAL RULES ARE "REASONABLY FORESEEABLE" IN LIGHT OF THE PROPOSED RULES

As the USPTO has consistently shown, the Final Rules are procedural and thus did not necessitate use of APA notice-and-comment procedures, although the agency voluntarily gave the public a chance to be heard. See USPTO Mem. at 59-60; USPTO GSK Opp. at 9-10. Consequently, the logical outgrowth doctrine is simply inapplicable.

Even assuming, however, that the APA required the USPTO to make its procedural rules available for notice and comment, the Final Rules were "reasonably foreseeable" from the Proposed Rules and thus satisfy the APA. Long Island Care at Home, Ltd. v. Coke, — U.S. —, 127 S. Ct. 2339, 2351 (2007); see 5 U.S.C. §§ 553(b), 553(b)(3) (requiring only that an agency provide "general notice of proposed rulemaking" including "either the terms or substance of the proposed rule"). This is not a case where the court needs to speculate whether the agency's notice was sufficient to inform the public of the kind of alternative it adopted; the public comments confirm that the notice in fact did so.

GSK first argues that the discussion in the USPTO's Notice of Proposed Rulemaking ("NPRM") of an earlier proposal for a hard limit of four independent claims and sixty total claims could not have put the public on notice of the Final Rules because the Proposed Rules distinguished that earlier approach and the USPTO never adopted it. See 71 Fed. Reg. at 62 (citing Changes to Implement the Patent Business Goals, 63 Fed. Reg. 53497, 53506-08 (Oct. 15, 1998)); GSK Opp. at 40. This argument lacks merit. First, the USPTO has never argued that its reference to the 1998 proposal alone gave the public notice of the Final Rules. See UPSTO Mem. at 61-62. Instead, the USPTO has always argued that its overall approach has not changed from the Proposed Rules to the Final Rules, as both set a threshold number of claims in an application beyond which an applicant must submit an ESD. Id. at 61. The USPTO simply noted the reference in the NPRM to the 1998 proposal because that proposal gave the public added notice of approaches the agency had considered. Id. The approach of the 1998 proposal was to use numerical thresholds and a cap. The USPTO did not ultimately adopt a cap in the Final Rules, but did pursue numerical thresholds similar to the 1998 proposal.

Second, the USPTO's discussion of the rules it proposed in 1998, along with its proposal of a representative claims approach, evidently did put the public on notice of the Final Rules, as numerous comments specifically suggested that the USPTO adopt an approach like the 5/25 Rule. GSK objects that the USPTO cited only two such comments and that the USPTO misconstrued the comments of the AIPLA. GSK Opp. at 41-42. As an initial matter, the USPTO properly characterized AIPLA's comments, which, in response to the representative claims approach, suggested that the USPTO impose a threshold number of claims that could be filed (6 independent/30 total) before triggering a "very high per claim cost." Id. Although "a very high per claim cost" is not identical to the filing of an ESD (it may actually be more severe), AIPLA's approach was consistent with the approach that the USPTO ultimately implemented.

Moreover, although the USPTO's opening brief cited only two exemplar comments, USPTO Mem. at 62 (citing A00673; A01835), these were by no means the only comments that the USPTO received suggesting a threshold number of independent/total claims before triggering the ESD requirement. To the contrary, the USPTO received a multitude of comments from organizations, law firms, patent practitioners, individual inventors, and major corporations all advocating approaches similar to that which the USPTO adopted. See A01292 (PPAC, 6/40); A01558-59 (K. Broom, 3/30 or 6/30); A01728 (S. Wigmore, 3/20); A01695 (D. Tanner, 12/50); A00734 (Altera, 3/20 or 6/40); A01390 (IBM, 3/30 or 6/30); A01410 (InterDigital, 10/60); A00692 (M. Haynes 6/30); A0757 (WARF, 6/40). Furthermore, the following entities (among many others) concurred with the comments submitted by AIPLA, which proposed a 6/30 threshold: BASF Aktiengesellschaft, A01359; Pfizer, A01470; and Texas Instruments, A01479. The USPTO's consistent approach throughout the rulemaking process, that is, establishing a threshold number of claims that trigger the ESD requirement, demonstrates the reasonable foreseeability of the Final rules.[47] Long Island, 127 S. Ct. at 2351. The numerous comments received in response to the NPRM confirm that foreseeability.

Tafas baldly asserts that there were "many substantive changes" in the Final Rules from the Proposed Rules, but, like in his summary judgment motion, he fails to explain why the Final Rules were not reasonably foreseeable in light of the Proposed Rules. See Tafas Opp. at 33. Observed differences are not themselves indicative of a logical outgrowth problem. City of Waukesha v. EPA, 320 F.3d 228, 245 (D.C. Cir. 2003) (explaining that a federal agency "undoubtedly has authority to promulgate a final rule that differs in some particulars from its proposed rule"). Tafas's failure to explain how the Final Rules are not a logical outgrowth of the Proposed Rules such that the USPTO could meaningfully respond should be fatal to his claim.[48]

In sum, although the Final Rules differ in some respects from the Proposed Rules, those differences were the direct result of the USPTO's consideration of and response to the concerns of the public. The Final Rules are consistent with the overall approach taken in the Proposed Rules and advocated in the submitted comments. Accordingly, the Court should reject Plaintiffs' logical outgrowth claims.

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[47] GSK also repeats its flawed math to arrive at its 1800% increase calculation. The USPTO extensively addressed the factual deficiency in this argument, and will not repeat the same here. See USPTO GSK Opp. at 43-44.

[48] Tafas asserts, in passing, a new logical outgrowth argument regarding first Office action final rejection ("FAFR") practice. Tafas Opp. at 34. To the extent the Court entertains it, his claim is misplaced because FAFR practice is not the result of any rule, or change in rule. See USPTO Tafas Opp. at 12-13. Rather, the commentary in the Proposed Rules indicated that the "practice" of making initial rejections final under certain limited circumstances identified in MPEP § 706.07 (essentially where an applicant has filed a continuation but not done anything else to substantively advance prosecution) would be discontinued if the Proposed Rules, which provided for a single continuation, were adopted. Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48, 51 (Jan. 3, 2006). Because the Final Rules increased the number of continuations that could be filed, however, the Office noted that the practice would be maintained. 72 Fed. Reg. at 46722. Thus, "another swipe at the ball," see Tafas Opp. at 34, has not been removed because the Final Rules provide for more continuations than did the Proposed Rules. Moreover, even if the first action final practice were the subject of a rule, the failure to adopt a proposed rule is certainly foreseeable. Indeed, that is precisely what happened in Long Island. See 127 S. Ct. 2339, 2351 ("Since the proposed rule was simply a proposal, its presence meant that the Department was considering the matter; after that consideration the Department might choose to adopt the proposal or withdraw it.").

VIII. THE USPTO COMPLIED WITH THE REGULATORY FLEXIBILITY ACT

The administrative record amply demonstrates that the USPTO properly certified that the Final Rules will not have a significant economic impact on a substantial number of small entities. Specifically, the USPTO analyzed the potential economic effect of the Final Rules on small entities, considered alternative approaches and explained why it chose not to implement them, and adopted certain modifications to minimize economic impact. See USPTO Tafas Opp. at 27-37. The USPTO's certification, therefore, constitutes a reasonable, good faith analysis consistent with the obligations mandated under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-612. U.S. Cellular Corp. v. FCC, 254 F.3d 78, 88 (D.C. Cir. 2001); Associated Fisheries of Me., Inc. v. Daley, 127 F.3d 104, 116 (1st Cir. 1997) ("The point is not whether the Secretary's judgments are beyond reproach, but whether he made a reasonable, good faith effort to canvass major options and weigh their probable effects."). Nothing more was required of the USPTO.

Tafas's opposition memorandum ignores the Office's extensive efforts in conducting an economic analysis of the Proposed Rules and its consideration of the relevant RFA factors. Instead, relying exclusively upon extra-record material, Tafas criticizes the particular economic models the Office used to support its RFA certification. The use of such extra-record evidence is entirely improper and this Court should accordingly disregard it.[49] Furthermore, as extensively

[49] The USPTO's Motion to Strike sought to strike, *inter alia*, Tafas's extra-record evidence and the parts of his summary judgment brief that rely on them to assert that the Office failed to comply with the RFA. The USPTO also moved to strike Exhibit 21 of Polestar's *amicus* brief, which is an extra-record declaration of Richard Belzer opining that the Office's

explained in the USPTO's opening and opposition memoranda, Tafas's contentions again fail to acknowledge that "[t]he RFA 'imposes no substantive requirements on an agency; rather, its requirements are 'purely procedural' in nature.'" Tafas II, 2008 WL 112043, at *9 (quoting Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric., 415 F.3d 1078, 1100 (9th Cir. 2005)); Alenco Commc'ns Inc. v. FCC, 201 F.3d 608, 625 (5th Cir. 2000) ("The RFA is a procedural rather than substantive agency mandate"). Because its certification thoroughly demonstrates that the Office complied with all the procedural requirements mandated by the RFA, the USPTO is entitled to summary judgment. Tafas's renewed complaints that the Office used improper economic modeling and underestimated certain economic variables – which, as previously explained, lack merit – constitute substantive challenges and are therefore inappropriate. See, e.g., Alenco Comm'n, 201 F.3d at 625. The USPTO will respond to Tafas's complaints, however, again only out of an abundance of caution.

Tafas's first attack on the USPTO's economic analysis seeks, inappropriately, to incorporate the complaints raised in the *amicus* brief filed by Dr. Ron Katznelson. Tafas Opp. at 37-38; see Tafas I, 511 F. Supp. 2d at 660-61 (explaining that the Court "may not consider legal issues or arguments that were not also raised by Plaintiffs"). Specifically, Tafas asserts that the USPTO's certification: (1) understated the number of small entities affected by the Claims rule; (2) failed to identify "fundamental factors" that govern the costs associated with preparing an ESD; (3) inappropriately assumed that small entities file only one patent application every twenty

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RFA analysis contained statistical flaws. Polestar Br., Ex. 21. For the same reasons as set forth in that Motion, this Court should not consider the extra-record material attached to and referenced in Tafas's opposition memorandum. As the USPTO observed in its Motion, this Court has already held that "the existing administrative record is sufficient" for "this Court to determine whether the USPTO made a 'reasonable, good faith effort' to comply with the RFA's procedural requirements." Tafas II, 2008 WL 112043 at *9 (citing 72 Fed. Reg. 46830-35; A07203-A08329).

years; (4) ignored the economic burdens of rebutting the presumption of patentably indistinct claims; and (5) failed to analyze or consider other undefined "important aspects of the problem." See Tafas Opp. at 37-38. The USPTO exhaustively responded to each of these meritless contentions in its opposition memorandum. See USPTO Tafas Opp. at 32-36. As the USPTO demonstrated, even a cursory review of its RFA analysis revealed that these assertions lacked any factual basis in the record, and moreover, that each aspect of the certification that Katznelson (and now Tafas) challenged constitutes a reasonable exercise of the USPTO's discretion. See id.; see also Carpenter v. Sec'y of Veterans Affairs, 343 F.3d 1347, 1357 (Fed. Cir. 2003) (applying an "abuse of discretion" standard in reviewing an RFA certification).

Tafas's remaining attack on the USPTO's certification relies on arguments asserted in the declaration of Richard Belzer, Ph.D., ("Belzer declaration"), which is attached to the Polestar *amicus* brief. See Tafas Opp. at 39-41. The Court should disregard these arguments, which rely on extra-record materials that are not properly before the Court and are adopted from *amici*. In any event, just like the criticisms asserted by Katznelson and now adopted by Tafas, Belzer's arguments lack merit.

Tafas first cites Belzer's assertion that, in light of the paperwork burden alone, the Proposed Rules would have met the test for being an "economically significant" regulatory action under Executive Order 12,866, § 3(f)(1). Tafas Opp. at 39. Whether the USPTO failed to comply with the Executive Order is irrelevant to the question of whether the Office met its obligations under the RFA. In fact, Section 10 of the Executive Order expressly precludes judicial review of the agency's compliance with that Order. See Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993) (providing in relevant part that the "order is intended only to improve the internal management of the Federal Government" and "does not create any right or benefit, substantive or procedural, enforceable at law or equity"). In any event, as set forth above, courts review agency compliance with the RFA not by looking to agency compliance with Executive Order 12,866, but rather by examining whether the agency has satisfied its procedural obligations set forth under the Act. See, e.g., U.S. Cellular Corp, 254 F.3d at 88; Alenco Commc'ns Inc., 201 F.3d at 625. Thus, the mere invocation of Executive Order 12,866, and the allegations that the agency failed to comply with that Order, do not demonstrate that there are any deficiencies in the Office's RFA certification.

Tafas next cites Belzer's bald assertion that the USPTO failed to conduct a social cost/benefit analysis of the Proposed Rules and failed to consider reasonably feasible alternatives. See Tafas Opp. at 40. This argument lacks any basis in the administrative record. To the contrary, the RFA certification – as well as the entire administrative record – amply demonstrates that the USPTO considered both the expected benefits that the rules would provide to the Office and the public, as well as the potential costs they would impose on both large *and* small entities. For example, as the USPTO's opening memorandum sets forth in greater detail, the Federal Register notice explains the gains in efficiency the agency reasonably expects to achieve from the Final Rules, as well as how each rule will achieve them. See, e.g., USPTO Mem. at 34-49; 72 Fed. Reg. at 46718-21, 46754, 46825. The Federal Register explains how both the claims and continuations rules will induce applicants to engage in more diligent and focused prosecution, thereby permitting the Office to examine more applications with greater efficiency and reduced examiner error. See, e.g., 72 Fed. Reg. at 46720-21, 46754. Further, the RFA certification provides a thorough analysis of significant alternatives the Office considered and an equally thorough explanation regarding why the Office adopted some alternatives, but chose not to pursue others. A08301-02; see also USPTO Tafas Opp. at 29-32. Belzer's assertions are simply without merit.

Finally, Tafas cites Belzer's complaint that the USPTO's RFA analysis is "intrinsically flawed" because it improperly assumed that the filing of three applications with 5/25 claims (one initial application and two continuations) was "equivalent" to the filing of a single application with 15/75 claims. See Tafas Opp. at 40-41. Belzer argues that the RFA certification contains no analytic support for this assumption, and further, that a number of unrealistic conditions must hold true in order to support the assumption. Id. Belzer's arguments misapprehend the relevant data underlying the USPTO's RFA certification. The USPTO never stated or assumed – and Tafas has not provided any citation to the contrary – that an application containing 15/75 claims was the "equivalent" of three applications containing 5/25 claims. Rather, the USPTO merely noted that Final Rules 75 and 78 provide a means by which an applicant may claim up to fifteen independent claims and seventy-five total claims to an invention without providing either an examination support document or a justification. See 72 Fed. Reg. 46718. Nothing in the RFA certification expressly or impliedly indicates that the two circumstances are "equivalent" for purposes of determining the economic effect of the Final Rules. In any event, whether or not the two are equal is irrelevant to the RFA analysis, as the Office's certification does not depend on assuming that an application with 15/75 claims is equal to three applications with 5/25 claims.

In the end, the Court need not reach the substantive issues that Tafas has raised in his opposition memorandum because the RFA is a procedural statute. Even if it does, however, the USPTO's certification constituted a reasonable, good faith analysis entirely consistent with the RFA's procedural requirements. U.S. Cellular Corp., 254 F.3d at 89; Associated Fisheries of Me., Inc., 127 F.3d at 116. Accordingly, Tafas's RFA claim fails.

CONCLUSION

Because the Final Rules are lawful in every respect, the Court should grant the USPTO's motions for summary judgment against both Plaintiffs, deny Plaintiffs' summary judgment motions, and allow the USPTO to bring about the critical reforms the Final Rules aim to achieve.

Respectfully submitted,

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